CE

BacT/ALERT 3D™ 60

User Manual

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This product and its documentation complies with the In Vitro Diagnostic Medical Device Directive 98/79/EC.

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Warranty

Seller, bioMérieux, Inc., warrants the BacT/ALERT® 3D 60 instrument (the "instrument") to the original purchaser for a period of one (1) year after date of installation against defects in material and workmanship and defects arising from failure to conform to specifications applicable on the date of installation. Seller further agrees to correct, either by repair, or, at its election, by replacement, any such defect found on examination to have occurred, under normal use and service, during such one (1) year period, provided Seller is promptly notified in writing upon discovery of such defect.

Seller shall not be liable under this Warranty for any defect arising from abuse of the system, failure to operate and maintain the system in accordance with the documentation included with the Instrument, including repair service, alteration or modification of the system by any person other than service personnel of bioMérieux, Inc., or Seller; or use of modified, changed, or previously used disposables.

The Warranty of Seller set forth above and the obligations and liabilities of Seller thereunder are exclusive and in lieu of all other remedies or warranties, express or implied, arising by law or otherwise, with respect to the system delivered hereunder (including without limitation any obligation of Seller with respect to merchantability, fitness for particular purpose, and consequential damages, and whether or not occasioned by Seller's negligence).

This Warranty shall not be extended or altered except by written instrument signed by Seller.

All of the product elements in the Seller's Instrument and the total instrument are warranted to be new or equivalent to new for the full product warranty period of one year. Disposables and replacement items with a normal life expectancy of less than one (1) year, such as batteries and bulbs, are excluded from this warranty.

STANDARD SYMBOLS

The following table presents symbols that may appear in the instructions for use or on the instrument, package inserts, or packaging.

	CE-Marking of Conformity
	Consult Instructions for Use
	Use by
	Manufacturer
	Date of manufacture
	Contains sufficient for <*n*> tests
	Keep dry
	Fragile, handle with care
	Caution, consult accompanying documents
	Biological risks
	Electric shock warning

	Radiation warning
	Potential pinch-point warning
	Laser
	Temperature limitation
	Upper limit of temperature
	Lower limit of temperature
IVD	In Vitro Diagnostic Medical Device
LOT	Batch code
EC REP	Authorized Representative in the European Community
REF	Catalog number
SN	Serial Number
	Do not reuse
	Recyclable
	Separate collection for waste electrical and electronic equipment

Very toxic

Corrosive

Sodium azide

Irritant

Positive control

Negative control

Keep away from sunlight

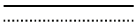
Protect from light

This way up

Do not stack

Humidity limitation

Fuse



Direct current

Alternating current

Both direct and alternating current

Three-phase alternating current

Earth (ground) terminal

Protective conductor terminal

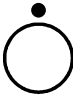
Frame or chassis terminal

Equipotentiality

ON (supply)

OFF (supply)

ON (only for a component of the system equipment)



OFF (only for a component of the system equipment)

Equipment protected throughout by double insulation or reinforced insulation (Equivalent to Class II of IEC 536)

Potential tip over/crush hazard

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HOW TO USE THIS MANUAL 1

About This Chapter

This chapter gives you important information about the BacT/ALERT® 3D 60 system and how to use this manual. We recommend that you read this chapter first.

IMPORTANT: ***Read this manual carefully before you attempt to operate the BacT/ALERT® 3D 60 system.***

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Additional Supplies • 1-3
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Intended Audience

The BacT/ALERT® 3D 60 system and this manual are intended for laboratory use by trained, professional users.

Purpose of the BacT/ALERT® 3D 60 System

The BacT/ALERT® 3D 60 Microbial Detection System is a totally automated test system capable of incubating, agitating, and continuously monitoring aerobic and anaerobic media inoculated with patient specimens suspected of having bacteremia, fungemia, and/or mycobacteremia.

CAUTION: bioMérieux shall not be liable as to any defect arising from abuse of the instrument, failure to operate and maintain the instrument in accordance with the User Manual, operation of the instrument by a person who has not been trained in its operation by bioMérieux, repair, service, alteration or modification of the instrument by any person other than service personnel of bioMérieux, or modification, change or reuse of the disposables supplied by bioMérieux for use in the instrument.

CAUTION: This BacT/ALERT® 3D User Manual is only intended for use with B.30 Software or higher. The software version B.30 (or higher) is displayed at the bottom of the instrument icon on the Main screen.

CAUTION: All figures depicting monitor screens are examples only. Actual screens may differ to the extent they are affected by the actual data entered by the user, or actual data transmitted to the instrument over the LIS interface, or actual data generated by the instrument.

CAUTION: Regarding section "Entering Report Labels," the user is solely responsible for the choice of customized report label text and for validating that the intended label text appears in all associated reports. *bioMérieux shall not be liable for any consequences resulting from misinterpretation of customized report labels*.

Additional Supplies

Contact bioMérieux or your local vendor for laboratory supplies and accessories.

Purpose of This Manual

This manual focuses on the BacT/ALERT® 3D 60 software application and how you use it in your workflow. It contains step-by-step procedures for using your BacT/ALERT® 3D 60 system.

By using these procedures, you can perform all the functions required to operate your system, including:

- accessing the BacT/ALERT® 3D 60 software
- system monitoring
- entering order information (where applicable)
- loading and unloading bottles
- viewing and printing data
- LIS interaction with the BacT/ALERT® 3D 60 SelectLink
- accessing the Setup screen

Note: *Screens and figures are intended for illustrative purposes only and are not to be construed as representations of actual test data, results, or components. Screens and components are not shown to scale.*

Manual Organization

This manual is organized by chapters. Chapters are organized according to the order of menu commands in the software application.

Chapter 1, How To Use This Manual — Provides an introduction to the BacT/ALERT® 3D 60 system and how to use this manual. It is recommended that you read this chapter first.

Chapter 2, System Overview — This chapter gives you a complete description of the different BacT/ALERT® 3D 60 hardware and software configurations available. Also, the monitor screens are listed along with a description of common screen elements.

Chapter 3, System Installation — Provides detailed instructions on how to install the instrument and perform functional tests.

Chapter 4, Basic Functions — Introduces you to the Main screen and shows you how to perform basic functions (ex. enter data, view faults, view the Cell Status screen, load/unload bottles, etc.). This chapter also introduces you to the Setup screen and the associated function buttons.

Chapter 5, Editing Test Data — Explains how to access bottle data for loaded and unloaded bottles using the Edit Bottle Detail screen. This chapter shows you how to view and edit bottle data.

Chapter 6, Software Configuration — Explains how to configure the software for your specific needs. This chapter shows you how to set the maximum test time, set the audible alarms, change the system password, initiate a manual backup, configure report screens, and view and print calibration data.

Chapter 7, System Maintenance — This chapter provides you with procedures on how to perform maintenance on the BacT/ALERT® 3D 60 hardware and software.

Chapter 8, System Troubleshooting — Describes the different types of instrument fault, instrument status and operator error codes, as well as bottle and user output device problems, you may encounter when using the instrument. Cause(s) and solutions(s) for each type of fault/error/problem are also listed.

Chapter 9, 21 CFR Part 11 Mode — This chapter explains how to log in and out of the instrument while in 21 CFR Part 11 mode, as well as instructions for configuring users (ex. adding or deleting a user, or clearing a user password).

This chapter also describes the events recorded in the audit trail and how to retrieve the audit trail.

Chapter 10, Mycobacterial Testing — This chapter provides you with a complete description of the of the BacT/ALERT® 3D 60 instrument when it is configured for Mycobacterial (MB) functions.

Appendix A, BacT/ALERT® 3D 60 Unpacking Instructions — Contains a diagram illustrating how to unpack the instrument.

Appendix B, BacT/ALERT® 3D 60 Part Checklist — To use when verifying and inspecting kit contents.

Appendix C, BacT/ALERT® 3D 60 Installation Checklist — To use when installing the instrument.

Appendix D, International Character Entry — Explains how to enter international characters on the BacT/ALERT® 3D 60 instrument.

Appendix E, Bottle Quality Control — This chapter provides you with a description of the BacT/ALERT® 3D 60 culture bottle along with a quality control procedure.

Glossary — An alphabetized list of frequently used terms along with a definition for each term.

Chapter Organization

All chapters include the following:

- *About This Chapter* — Brief description of the chapter's content and purpose.
- *Chapter Contents* — A table of contents for the chapter.
- *Descriptions and/or Procedures* — Chapters contain descriptions and procedures appropriate to their subject matter. See the Manual Organization section in this chapter for more information.
- *Background Information*, where applicable and useful.

Finding Topics

This manual uses several methods to help you find information and keep your bearings.

Table of Contents — Located at the front of the manual. It contains the titles of all chapters/appendices and their sections, and the page number of each title and section.

List of Figures — Located at the front of the manual. It contains a list of all figures in the manual and the page number of each figure.

List of Tables — Located at the front of the manual. It contains a list of all tables in the manual and the page number of each table.

Chapter Contents — Located at the front of each chapter. It lists all sections in the chapter and their page numbers.

Page Headers — Located at the top of each page. There are two parts to a header: the chapter title and the primary section title.

Page Footers — Located at the bottom of each page. There are three parts to a footer: the manual's title, the chapter's part number, and the page number.

Index — Located at the back of the manual. It contains topical entries and their page numbers.

Typographic and Usage Conventions

Name and Titles

Button, icon and field names are in Proper Case, bold.

Example: Click the **Select Maximum Test Time** button.

The names of windows and screens are in Proper Case, but are not bolded.

Example: The Set Maximum Test Time screen...

Click

This manual uses the word "click" to refer to using a mouse to choose or select a text entry field, button, or option.

Example: Click **OK**.

See the Select section in this chapter for more information

Press

This manual uses the word “press” to refer to pressing a key on the keyboard in order to initiate action in the firmware.

Keyboard entries are in Proper Case and bolded (ex. **Ctrl**). If two keys are to be pressed simultaneously, they will be separated with a plus sign (ex. press **Ctrl** + **Alt** + **Delete**).

Procedural Steps

Steps in procedures are sequentially numbered. A bullet list in a step indicates options.

Sections that contain procedures are denoted by the Procedure icon in the margin.

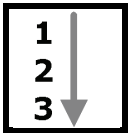


Figure 1-1: Procedure Icon

References

References to chapter and section titles in this manual are in Proper Case.

Example: See Chapter 7, Software Configuration.

References to other manuals are in Proper Case and italic.

Example: See the *BacT/ALERT® 3D 60 Service Manual*.

Select

The word “select” is generally used for selecting user interface navigation.

Example: Select the appropriate bottle type from the **Media Type** scroll button.

User Input

Instructions for user input begin with the word “type” or “enter.” This manual uses bold for literal user input and italic for placeholders.

Example of a Literal User Input: Enter the Software Exit Password **24313124**.

In this example, you are to type exactly what you see on the page (**24313124** in this example).

Example of a Placeholder: Enter your *password* before you...

In this example, you are to type your assigned password.

Warnings, Cautions, and Information

This manual uses different types of symbols to alert you to important information. Symbols and their associated information are labeled in text where they occur and set off from surrounding paragraphs, as shown in the following examples.

WARNING

Warning is a statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of a device.

CAUTION: Caution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. Where applicable, a caution statement may include a precaution that should be taken to avoid the hazard.

IMPORTANT: ***Important relates to content presented in this manual. It is used to reinforce the importance of your understanding or remembering something.***

Note: *Note supplies additional information about a topic.*

SYSTEM OVERVIEW 2

About This Chapter

This chapter gives you a complete description of the different BacT/ALERT® 3D 60 hardware and software configurations available. Also, the monitor screens are listed along with a description of common screen elements.

Chapter Contents

Introduction • 2-2

Hardware Configuration • 2-2
Software Configuration Options • 2-2
21 CFR Part 11 and HIPAA • 2-3
Theory Of Operation • 2-3
Electrical Warnings • 2-4
Electrical Grounding • 2-6
Electrical and Electronic Recycling • 2-7
Fuse Replacement • 2-7

BacT/ALERT® 3D 60 Hardware • 2-8

Instrument • 2-8
Instrument Specifications • 2-11
Instrument Environmental Requirements • 2-12
Instrument Installation and Setup • 2-13

BacT/ALERT® 3D 60 Software • 2-13

Monitor Screens • 2-13
Common Screen Elements • 2-14

Introduction

The BacT/ALERT® 3D 60 is the next generation of BacT/ALERT® instrumentation with comparable sensitivity and specificity to the BacT/ALERT® 3D systems. The system is non-invasive. A monitor screen in conjunction with a mouse allows for a text-free user interface to direct rapid loading and unloading of individual test samples.

Once placed in the unit, handling of a specimen bottle is not required until a result is obtained. Immediately upon detection, positive results are indicated visually on the unit's monitor and, if desired, by an audible beep. If no microbial growth is present after a specified time, a specimen is determined to be negative. The system will also indicate the negative samples that are ready for removal when prompted. Because the system handles bottles individually, testing of new specimens may begin at any time. The system also utilizes barcode technology to assist in specimen and data tracking.

The disposable culture bottles contain a liquid emulsion sensor that is monitored continuously using solid-state photodetectors. In addition, the bottles contain media and atmosphere which promote the recovery of a wide variety of microorganisms without venting.

Hardware Configuration

The BacT/ALERT® 3D 60 utilizes a stand-alone instrument that has 60 cells for bottle monitoring.

Software Configuration Options

The instrument supervises the reading of the sensors and contains decision-making algorithms to determine which specimens are positive or negative. The instrument can be arranged in one of two BacT/ALERT® 3D 60 software configurations:

- **BacT/ALERT® 3D Select configuration** —The BacT/ALERT® 3D 60 is not connected to a Laboratory Information System (LIS). Limited data management is available through the system.
- **BacT/ALERT® 3D SelectLink configuration** — The BacT/ALERT® 3D 60 is connected directly to an LIS. Limited data management is available through the system.

The software configuration is listed at the top of all screens (see Figure 4-1, Main Screen) except for the Edit Cell Contents or View Cell Contents screen (see Figure 5-1, Edit Cell Contents Screen). The background color will also

indicate the configuration unless there is an error condition or a loaded positive bottle (see Main Screen Introduction in Chapter 4):

- Blue — BacT/ALERT® 3D Select configuration
- Green — BacT/ALERT® 3D SelectLink configuration

21 CFR Part 11 and HIPAA

The BacT/ALERT® 3D 60 Version B.30 or higher product release provides compatibility with 21 CFR Part 11 and Health Insurance and Portability and Accountability Act (HIPAA) requirements.

When installed, the BacT/ALERT® 3D 60 instrument can be configured to operate in 21 CFR Part 11 mode. If 21 CFR Part 11 mode is enabled, you will need to enter a user name and password to access all functions available to the user (see Log In/Out of System — 21 CFR Part 11 Mode in Chapter 9).

To meet HIPAA requirements, a password is required to view and print test data. These functions include access to the **Print**, **Report Label Entry**, **Report Configuration**, **Calibration Report** and **Calibration History** buttons. These buttons are accessed via a Report Selection screen (see Figure 4-10). See the topic, Configuring Report Screens in Chapter 6 for further information.

Theory Of Operation

Principle of Detection

If microorganisms are present in the test sample, carbon dioxide is produced as the microorganisms metabolize the substrates in the culture medium. When growth of the microorganisms produces CO_2, the color of the sensor in the bottom of each culture bottle changes from blue-green to a lighter color.

A light-emitting diode (LED) projects light onto the sensor. The light reflected is measured by a photodetector. As more CO_2 is generated, more light is reflected. This information is compared to the initial CO_2 level in the bottle. If there is a high initial CO_2 content, an unusually high rate of CO_2 production, and/or a sustained production of CO_2, the sample is determined to be positive.

Mycobacterial growth in the BacT/ALERT® MP Bottles may also be determined positive by the delta or a slow sustained change of CO_2 production. If the CO_2 level does not change significantly after a specified number of days at optimal conditions, the sample is determined to be negative.

CAUTION: Unloading or manipulating the bottles when not indicated by the system may interfere with critical bottle readings.

Electrical Warnings

The BacT/ALERT® 3D 60 has been designed and tested in accordance with the standards listed below and has been supplied in a safe condition. A CB Certification and Construction File have been established for the apparatus.

- UL 61010-1 (2nd Edition, 2001), *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements*
- IEC 61010-1 (2nd Edition, 2001), *Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use*
- IEC 61010-2-081 (1st Edition, 2001), *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*
- CAN/CSA-C22.2 No. 1010.1-92, *Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use*

WARNING

The user must adhere to the following warnings to ensure safe operation and to maintain the apparatus in a safe condition:

- **Ensure that the BacT/ALERT® 3D 60 instrument is configured for the correct voltage at the instrument's power entry port before turning on.**
- **Intentional interruption of the protective conductor inside or outside the apparatus, or disconnection of the protective ground terminal, is prohibited.**
- **Disconnect the apparatus from all voltage sources before it is opened for any adjustment, replacement, maintenance, or repair.**
- **Do not perform any adjustments, maintenance, or repairs of the opened apparatus while under voltage. If this is unavoidable, maintenance must be carried out only by a skilled person who is aware of the hazard involved.**
- **Ensure that only fuses with the required rated current and of the specified type are used for replacement. The use of makeshift fuses and the short-circuiting of fuse holders is prohibited.**
- **Whenever it is likely that the BacT/ALERT® 3D 60 instrument has been impaired, it should be rendered inoperative and secured against any unintended operation by disconnecting the power cord. If the presence of moisture is evident, turn off the machine at the breaker before removing the power cord and fuse.**
- **Do not forcibly remove the Zip® disk from the instrument. Forcibly removing the Zip® disk may cause damage to the Zip® disk or Zip® drive and may cause the system to lock up.**

WARNING

Contact your local bioMérieux Representative if any of the following conditions occur:

- **System shows visible damage.**
- **System fails to perform intended measurements.**
- **System has been subjected to storage under unfavorable conditions (ex. above 90% humidity, extreme temperatures, dusty environment, prolonged storage).**
- **System has been subjected to severe transport stresses.**

Electrical Grounding

An electrical ground is required for this instrument. Before installing the instrument, ensure a grounded wall receptacle is available. It must be plugged into a mating grounding type wall receptacle in accordance with the National Electrical Code and applicable local codes and ordinances for this type of installation (see Figure 2-1).

WARNING

Do not remove the power cord's ground prong under any circumstances.

WARNING

Do not insert any object, other than a Zip® disk, into the Zip® drive under any circumstances.

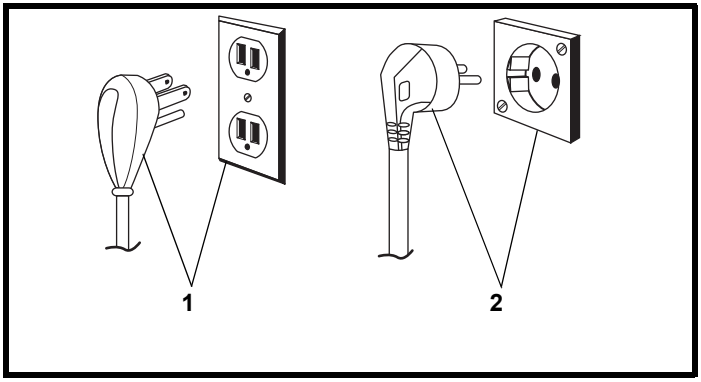


Figure 2-1: Electrical Grounding Requirements

1 — US Standard

2 — 220 Volt - European

Electrical and Electronic Recycling

WARNING

This statement only applies to European countries with regard to the waste electrical and electronic equipment European directive:

You can play an important role in contributing to reuse, recycling and other forms of recovery of waste electrical and electronic equipment. Sorting this type of waste significantly reduces potential negative effects on the environment and human health as a result of the presence of hazardous substances in electrical and electronic equipment.

At the end of the life cycle of this product, do not dispose of the product as unsorted municipal waste, even if it is decontaminated. It is imperative that you contact bioMérieux to assure for its appropriate disposal.

Fuse Replacement

The only user-servicable fuses in the BacT/ALERT® 3D 60 system are located in the Power Entry Module (see Setting the AC Power in Chapter 3). For all other internal fuses, contact your local bioMérieux Instrument Service Representative.

BacT/ALERT® 3D 60 Hardware

The BacT/ALERT® 3D 60 system includes a single instrument containing an incubation chamber, monitor, keyboard, UPS, printer, barcode reader, and a mouse. A door at the front of the instrument accesses the incubation chamber.

The incubation chamber contains up to three racks, each with a capacity for 20 culture bottles. The incubation chamber may be configured for either Mycobacteria (MB) or non-MB. Configuring the chamber for MB enables all three racks within the chamber to remain immobile. It also causes the **Instrument** icon on the Main screen to be labeled as MB.

Note: *The BacT/ALERT® 3D 60 software must also be configured to activate the MB status.*

Instrument

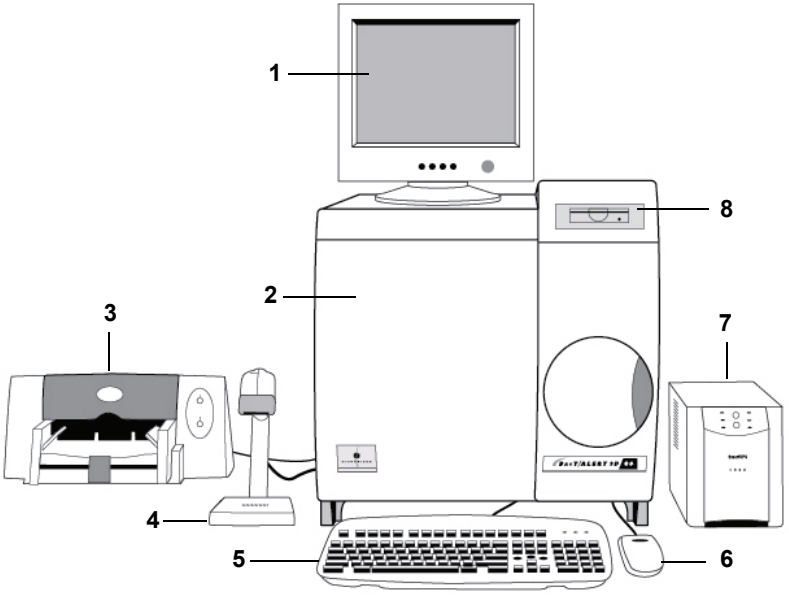


Figure 2-2: Instrument Front View

1 — Monitor
2 — Incubation Chamber
3 — Printer
4 — Barcode Reader
5 — Keyboard
6 — Mouse
7 — UPS
8 — Backup Drive

Monitor

Displays bottle and system information.

Barcode Reader

A Barcode Reader is used to scan bottle barcode labels to identify bottles and accession barcodes when loading or unloading.

Mouse

A mouse is used to move from one screen to another and to input data and selections.

Keyboard

Provides an alternate means of input. Serves as a backup input device should the barcode reader or mouse fail.

UPS

The UPS (Uninterruptible Power Supply) is external to the BacT/ALERT® 3D 60.

Backup Drive

The Backup Drive allows system backups to be made to either a Zip® disk or USB flash drive, depending on system configuration.

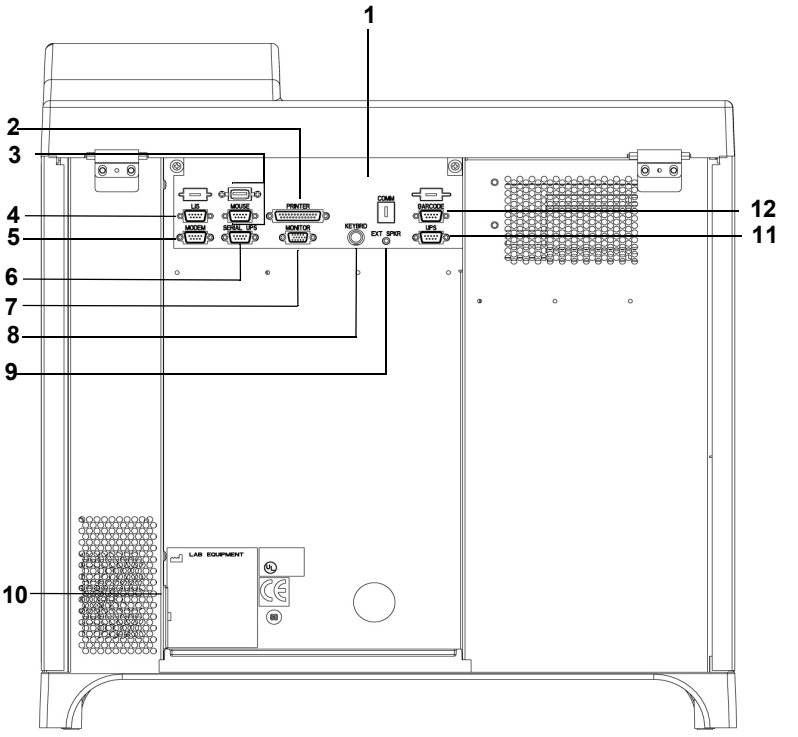


Figure 2-3: Instrument Rear View

1 — Communications Panel
2 — Printer Port
3 — Mouse Ports
4 — LIS Port
5 — Modem Port
6 — Serial UPS Port
7 — Monitor Port
8 — Keyboard Port
9 — External Speaker Port
10 — Power Entry Module
11 — UPS Port
12 — Barcode Reader Port

UPS Port

Used to connect an external UPS to the instrument. Located on the Communications Panel.

UPS Serial Port

Reserved for future use. Located on the Communications Panel.

Monitor Port

Port for connecting the monitor to the instrument. Located on the Communications Panel.

Mouse Ports

Used for connecting the mouse to the instrument. Located on the Communications Panel.

Keyboard Port

Port for connecting the keyboard to the instrument. Located on the Communications Panel.

Printer Port

Interface port (parallel) for connecting the printer to the instrument to produce hard copy reports. Located on the Communications Panel.

External Speaker Port

Port for connecting external speakers to the instrument. Available for order as a separate kit. Located on the Communications Panel.

Power Connector

Connector for alternating current (AC) power cord.

Power Entry Module

Turns the AC Power to the instrument On and Off.

Modem Port

Used to connect an external modem to the instrument allowing remote diagnosis of instrument problems. The external modem box should be in the **OFF** position when not in use by a bioMérieux Representative.

LIS Port

Used to connect the Instrument to a Laboratory Information System (LIS). Located on the Communications Panel.

Comm Port

Reserved for future use. Located on the Connection Panel.

Instrument Specifications

Electrical Power Services Requirements

- 100/120 Volts @ 50/60Hz
- 220/240 Volts @ 50/60 Hz

Power Consumed in Watts

- 115 Volts (380W max. — 255W Typical)
- 230 Volts (380W max. — 255W Typical)

Heat Dissipated

- 1300 BTU/Hr max. -- 870 BTU/Hr Typical

Sound Emission

- 50.8 dB

Instrument Dimensions

- Width — 22.75 in. (57.8 cm)
- Height — 24 in. (61 cm)
- Depth — 19.5 in. (49.5 cm)
- Weight (Unloaded) — 90 lbs. (41 Kg)
- Weight (Loaded) — 98 lbs. (45 Kg)

Instrument Environmental Requirements

Operating Temperature Range

- 10°C to 30°C (50°F to 86°F)

Storage Temperature Range

- -17°C to 57°C (0°F to 135°F)

Operating Humidity Range

- 10% to 90% relative humidity, non-condensing.

Storage Humidity Range

- 10% to 90% relative humidity, non-condensing.

Maximum Operating and Storage Altitude

- 6562 feet (2000 meters)

Pollution Degree 2 in accordance with IEC 664

Overvoltage Category II per IEC 664

Instrument Installation and Setup

For information on the Installation and Setup of the BacT/ALERT® 3D 60 instrument, see Chapter 3, System Installation.

BacT/ALERT® 3D 60 Software

Monitor Screens

The Main screen is normally visible on the Monitor, but other screens may be displayed to perform a variety of functions. Each screen has a screen ID number in the upper left-hand corner to cross-reference it to the following descriptions and instructions in this Manual. When selected, the Setup screen replaces the Main screen.

Screen ID Numbers

- 1.0 Main screen
- 1.1 View Cell Status screen
- 1.2 Change Maximum Test Time screen
- 1.3 User Login screen (21 CFR Part 11 mode only)
- 2.0 Setup screen
- 2.1 Set Date/Time screen
- 2.2 Enable/Disable Rack or Cell screen
- 2.3 Calibrate Temperature screen
- 2.4 Calibrate Cell screen
- 2.4.1 Cell Calibration Report screen
- 2.7 Set Maximum Test Time screen
- 2.8 Set Audible Alarm Options screen
- 2.9 Change Password screen
- 2.11 Select Bottle to Edit/Graph screen
- 2.11.1 Edit Bottle Detail screen
- 2.11.1.1 Edit Test Result
- 2.11.2 Graph Bottle Readings screen
- 2.11.2.1 Bottle Readings screen
- 2.12 Edit Cell Contents screen (2.11.1, 2.11.1.1, 2.11.2 and 2.11.2.1 can also be accessed from this screen)
- 2.13 View Incubation Chamber Information screen
- 2.14 Report Label Entry screen
- 2.15 Report Configuration screen
- 2.15.1 Report screen
- 2.16 Backup Management screen
- 2.17 Edit Data Relationships screens
- 2.19 Viewing and Printing Calibration Data screen
- 2.20 Bottle Type Customization screen

- 2.21 Report Selection screen
- 2.21.1 Calibration History screen
- 2.23 User Configuration screen (21 CFR Part 11 mode only)
- 2.23.1 Add User screen (21 CFR Part 11 mode only)
- 2.23.2 Delete User screen (21 CFR Part 11 mode only)
- 2.23.3 Change User Password screen (21 CFR Part 11 mode only)

Common Screen Elements

Icon

Graphic symbols used instead of text to convey information and concepts in the Monitor.

Button

- Appear as rectangular shapes which can be clicked to input choices or activate functions.
- Button function is indicated by icon displayed on button face.
- If a button is gray, then it is disabled and its associated function is unavailable.

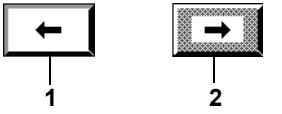


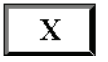
Figure 2-4: Button Examples

1 — Enabled Button

2 — Disabled Button

Common System Buttons

Table 2-1: Common System Buttons

	Check button – Accept changes, save data or entries on that particular screen.
	**Cancel** button – Discard changes or entries on that particular screen to keep the original values.
	Previous Screen Button – Return to the previous screen.
	Next Screen Button – Move to the next available screen.

Scroll Button

- Used for numeric entry and symbolic or media type selection.
- Consists of two small buttons and an area between them to display the current value.
- Clicking the top or bottom button of the scroll button displays the next higher or lower value.
- Adjacent scroll buttons provide entry for multi-digit values.

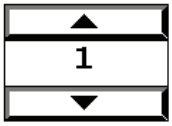


Figure 2-5: Scroll Button

Slidebar Switch

- Turns a function On or Off. The specific function is represented by a separate icon next to the slidebar.
- Clicking the right half of the icon moves the slidebar to the right, indicating an On selection (**1**).
- Clicking the left half of the icon moves the slidebar to the left, indicating an Off selection (**0**).

Figure 2-6: Slidebar Switch

Anchor Display/Scroll Buttons

- **Anchor Display** top or bottom buttons — Control whether the display stays anchored on the first or last line of the diagnostic output.
- **Line** scroll up or down buttons — Move the display area one line at a time (up or down). This function can also be performed by pressing the ↑ or ↓ key on the keyboard.
- **Page** scroll up or down buttons — Move the display area one page (up or down). This function can also be performed by pressing the **Page Up** or **Page Down** key on the keyboard.
- **Home**/**End** scroll buttons — Position the display area to the first or last line of the diagnostic output. This function can also be performed by pressing the **Home** or **End** key on the keyboard.

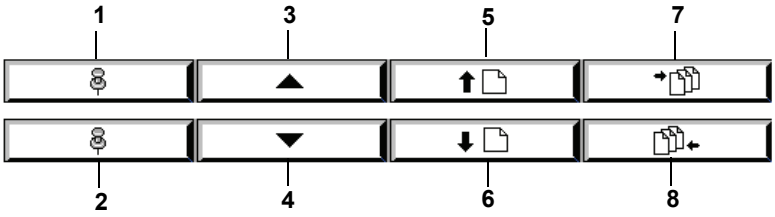


Figure 2-7: Anchor Display/Scroll Buttons

1 — Anchor Display Top Button
2 — Anchor Display Bottom Button
3 — Line Scroll Up Button
4 — Line Scroll Down Button
5 — Page Scroll Up Button
6 — Page Scroll Down Button
7 — Home Scroll Button
8 — End Scroll Button

Text Entry Field

A text entry field appears as a rectangular box that allows the user to enter text either manually via the keyboard or by scanning a barcode (see Text/ Data Entry in Chapter 4). The **Bottle ID** field on the Main screen is an example of a text field.

SYSTEM INSTALLATION 3

About This Chapter

This chapter provides you with detailed instructions on how to install the instrument and perform functional testing.

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Preparation • 3-2

Verifying Site Requirements Are Met • 3-2

Verifying Contents • 3-2

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Setting the AC Power • 3-3

Choosing Instrument Location • 3-6

Making Instrument Connections • 3-7

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Setting the Temperature • 3-10

Checking for Errors • 3-10

Functional Testing • 3-10

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Installing the Optional Restraint • 3-12

Preparation

Verifying Site Requirements Are Met

1) Review the mandatory requirements below to ensure they are met:

- Lab environment temperature and humidity are within specified tolerances.
  - Temperature is between 10°C – 30°C
  - Humidity is between 20% – 90%
- Unit is positioned away from direct sunlight and bright overhead lights.
- Telephone line for modem access is located within 25 feet.
- Floor or bench that is capable of supporting 126.0 lbs. (57.2 Kg) per instrument installed.
- Unobstructed clearance of 4 inches behind and 12 inches above the module.
- Verify that a dedicated AC circuit with proper voltage and current ratings for the instrument and UPS are available and located within 8 feet (see Instrument Specifications in Chapter 2).

2) Indicate that site requirements are met on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Verifying Contents

1) Unpack the contents of the BacT/ALERT® 3D 60 using the BacT/ALERT® 3D 60 Unpacking Instructions in Appendix A.

2) Verify and Inspect contents of the BacT/ALERT® 3D 60 for shipping damage using the BacT/ALERT® 3D 60 Part Checklist in Appendix B.

3) Indicate that contents are verified on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Installation

Setting the AC Power

WARNING

The BacT/ALERT® 3D 60 ships without a default voltage setting. The procedure that follows describes how to insert the fuse(s) for proper voltage setting. After installing proper fuse(s), discard the remaining fuse(s).

Note: *The Power Entry Module (805-0017-02) is located in the rear and lower left corner of the instrument.*

Note: *When configured for 115 VAC, the PEM has one 6.3 Amp 250V time-delay fuse (870-0008-25). In addition, a conversion clip is located across the neutral line in the fuse holder.*

Note: *When configured for 230 VAC, each PEM has two 5.0 Amp 250V time-delay fuses (870-0008-24).*

1) Ensure the instrument is powered down.

2) Ensure that the main power and interface cables are disconnected.

3) Open the PEM cover using a small flat blade screwdriver.

4) Slide out the fuse holder (see Figure 3-1).

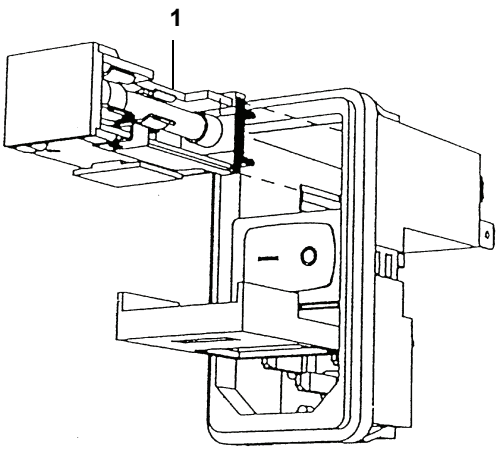

Figure 3-1: Power Entry Module with Fuse Holder Removed

1 — Note the fuse orientation to the rear of the fuse holder.

5) Install the fuse(s) for the proper voltage rating. Determine the proper fuse installation to use based on the Facility Power Ratings listed in Table 3-1.

Table 3-1: Facility Power Rating and Conversion Chart

Facility Power Rating	Configuration	Fuse(s) to Use
110 Volts AC	115 VAC	One (1) 6.3A 250V Time-Delay Fuse (Refer to Step a and Figure 3-2)
115 Volts AC	115 VAC	One (1) 6.3A 250V Time-Delay Fuse (Refer to Step a and Figure 3-2)
125 Volts AC	115 VAC	One (1) 6.3A 250V Time-Delay Fuse (Refer to Step a and Figure 3-2)
200 Volts AC	230 VAC	Two (2) 5.0A 250V Time-Delay fuses (Refer to Step b and Figure 3-3)
220 Volts AC	230 VAC	Two (2) 5.0A 250V Time-Delay fuses (Refer to Step b and Figure 3-3)
230 Volts AC	230 VAC	Two (2) 5.0A 250V Time-Delay fuses (Refer to Step b and Figure 3-3)
240 Volts AC	230 VAC	Two (2) 5.0A 250V Time-Delay fuses (Refer to Step b and Figure 3-3)

a. To configure the BacT/ALERT® 3D 60 for 115 VAC, refer to Figure 3-2 to install a 6.3A 250V time-delay fuse.

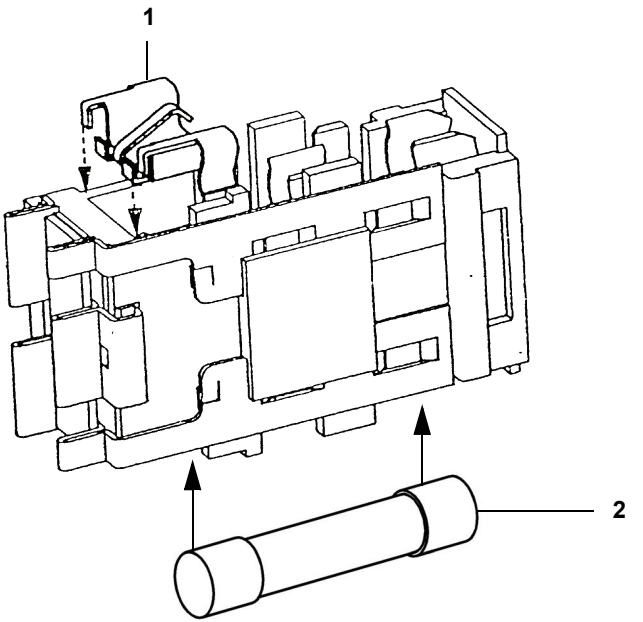

Figure 3-2: PEM with 115 VAC Version

1 — Conversion Clip **2 — 6.3A 250V Time-Delay Fuse**

b. To configure the BacT/ALERT® 3D 60 for 230 VAC, see Figure 3-3 to install the two 5.0A 250V time-delay fuses. Be sure to remove and dispose of the conversion clip, if one is present.

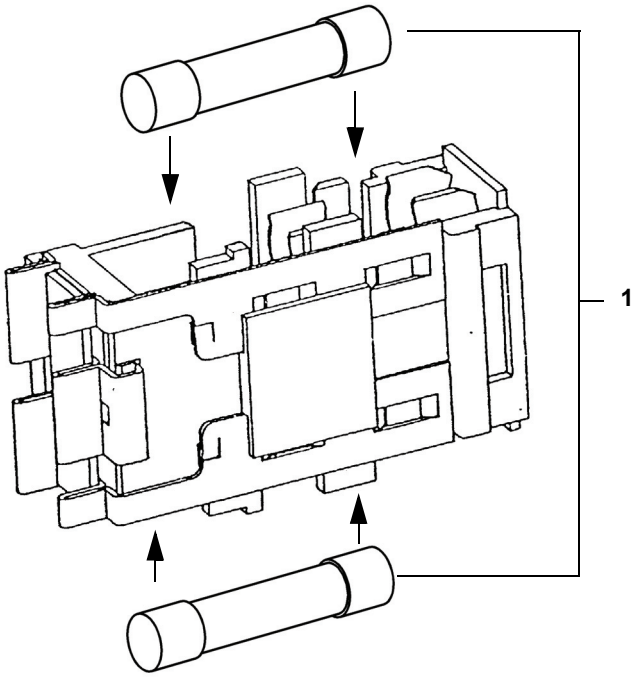

Figure 3-3: PEM with 230 VAC Version

1 — 5.0A 250V Time-Delay Fuses (2 required)

CAUTION: Installation of the 115V conversion clip in the 230 VAC version (see Figure 3-3) COULD RESULT IN DAMAGE to the unit. Ensure that the 115V conversion clip has been removed if installing the 230 VAC version.

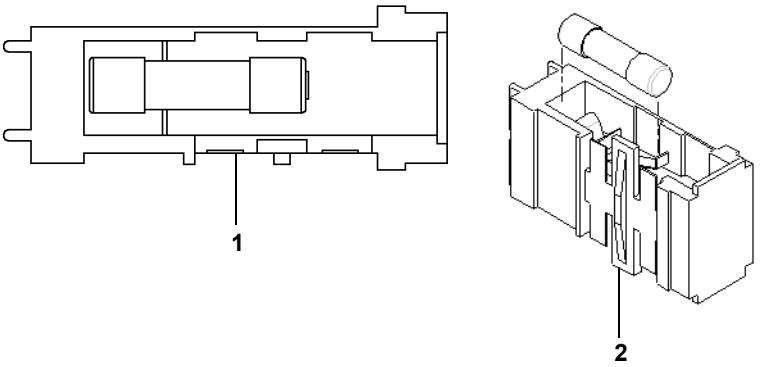

Figure 3-4: Additional Fuse Holder Views

1 — Top/Bottom View

2 — Side View

6) Reinstall the fuse holder.

7) Close the PEM cover.

8) Indicate that AC power is set on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Choosing Instrument Location

WARNING

The BacT/ALERT® 3D 60 has been designed to minimize risks associated with MB testing. However, to further reduce the risks of accidental exposure to infectious agents, additional precautions should be taken. It is strongly recommended that the instrument be placed in a laboratory used for the routine culture of *M. tuberculosis*. For activities involving the propagation and manipulation of *M. tuberculosis* or *Mycobacterium* species grown in culture, Biosafety Level 3 Practice, Containment Equipment, and Facilities are required as recommended by CDC and NIH guidelines.

At a minimum, the instrument should be placed in a contained environment with controlled access and a tuberculosis exposure control plan. The locations should have surfaces which can be easily decontaminated using an appropriate topical disinfectant. The instrument must not be placed in an open corridor or hallway that is accessible to the general public or the patient population.

If it is necessary to move or store the BacT/ALERT® 3D 60 System, contact bioMérieux Service for assistance.

1) Assemble and install the BacT/ALERT® 3D 60 Instrument in the specified installation location.

Note: *If countertop or other permanent (bolted) installation is required, see* *Installing the Optional Restraint on page 3-12*.

2) Indicate that location for instrument placement is chosen on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Making Instrument Connections

The following steps describe the connections that need to be made prior to powering up the BacT/ALERT® 3D 60. Figure 3-5 depicts the connections described in the following steps:

1) Connect the UPS battery per the instructions on the UPS. Place the UPS near the instrument. Connect the UPS serial cable to the 9-pin connector on the rear of the UPS and the other end to the UPS connector (not Serial UPS) on the 3D 60 instrument Communications panel. UPS port connection is shown in Figure 3-5.

Note: *The 9-Pin cable packed with the UPS should not be used and should be discarded. Use the UPS Serial Cable (9-Pin) provided in the accessory kit.*

2) Connect the 3D 60 instrument's main power cord into the properly rated UPS AC receptacle labeled as **Surge with Battery Backup**.

3) Plug the UPS main power cable into the properly rated AC wall outlet.

4) Connect the external speaker cable (if external speakers are installed) into the **Ext Spkr** jack on the Communications panel (not supplied — optional). External speaker connection is shown in Figure 3-5.

5) Plug in the external speaker's AC power cord into the properly rated AC wall outlet (not supplied — optional).

6) Plug in the monitor's15-pin cable into the **Monitor** port on the Communications panel (not supplied — optional). Monitor port connection is shown in Figure 3-5.

7) Plug in the monitor main power cable to the properly rated UPS AC receptacle labeled as **Surge with Battery Backup**.

8) Connect the keyboard cable into the **Keybrd** port on the Communications panel. Keyboard port connection is shown in Figure 3-5.

9) Connect the printer's parallel cable into the **Printer** port on the Communications panel. Printer port connection is shown in Figure 3-5.

10) Plug in the printer's main power cord into the UPS AC receptacle for **Surge Only** (no **Battery Backup**).

11) Connect the modem's communications interface cable to the **Modem** port on the Communications panel. Modem port connection is shown in Figure 3-5.

12) Connect the modem telephone cable to the **Jack** port on the modem (if supplied and installed).

13) Plug in the modem's power adapter into the modem. Plug in the main power cord from the adapter into the properly rated AC wall outlet (if supplied and installed).

14) Connect the barcode scanner's communications cable into the **Barcode** port on the Communications panel. Port connection is shown in Figure 3-5.

15) Connect the mouse cable into the applicable **Mouse** port on the Communications panel. Port connections are shown in Figure 3-5.

16) Indicate that all instrument connections are complete on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

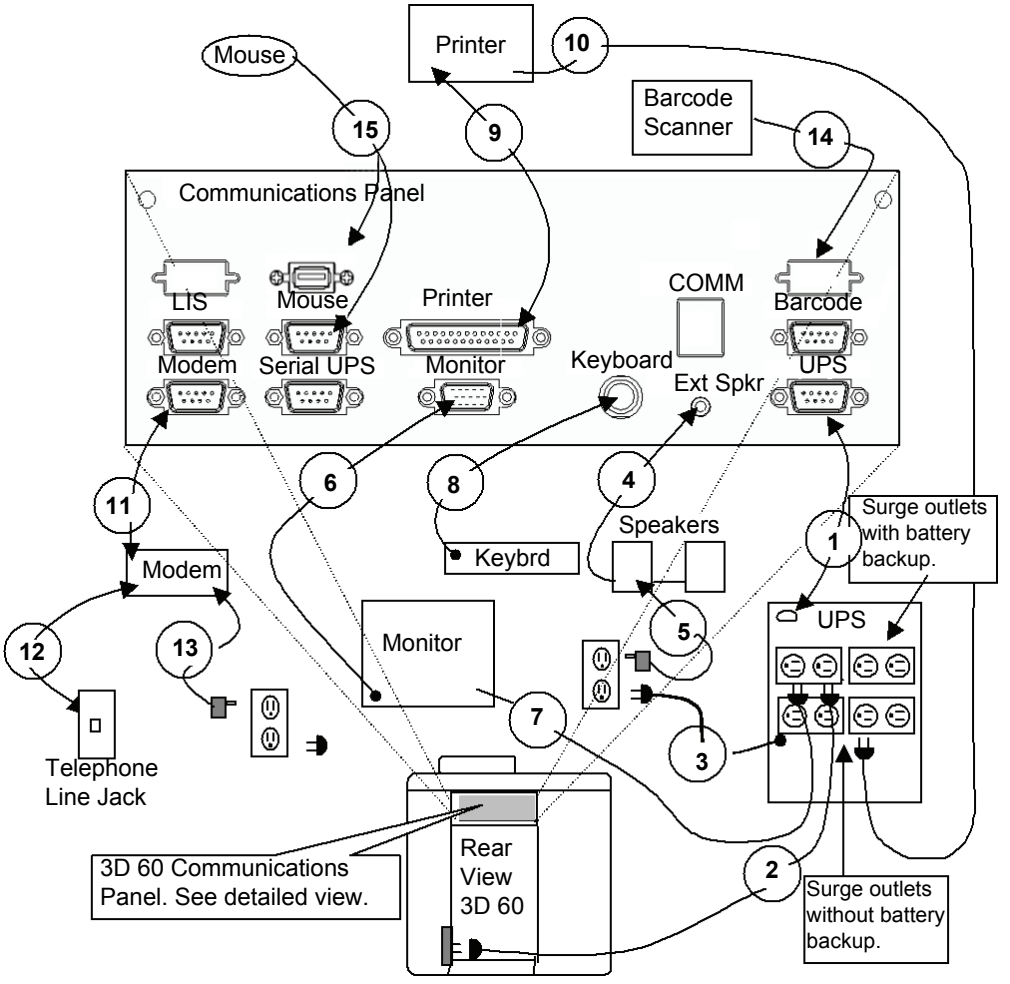

Figure 3-5: Installation and Setup Diagram — Port and Power Connections

Powering Up the Instrument

1
2
3

1) Turn the UPS switch **ON**.

2) Power up the instrument by turning on the Main Power switch on the rear of the instrument.

3) Power up the monitor, modem, and printer.

4) Turn on the electric reference thermometer, if applicable, making sure that it is set for Celsius.

5) Indicate that the instrument is powered up on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Configuring the Instrument

1) Verify that the screen title **Select** or **SelectLink** is correctly displayed.

2) Set up and verify maximum test times (see Setting the Maximum Test Time in Chapter 6).

3) Ensure that the lab supervisor is able to log onto the system with the password **1234**.

Note: *To change the password, see Changing the System Password in Chapter 6.*

4) Set the displayed date/time to reflect the current date and time in the lab (see Setting and Formatting the System Date and Time in Chapter 7).

5) Verify that each component is enabled by viewing the Main screen. Any disabled component will be displayed by gray "hash marks" denoting the disabled rack or individual cells within the rack. Use the Enable/Disable Rack, and Cell screen to enable each, accordingly (see Enabling and Disabling Racks and Cells in Chapter 7).

6) Indicate that instrument configuration is completed on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Setting the Temperature

1) Set the instrument operating temperature. Once the temperature has stabilized (4 hours), calibrate the actual instrument temperature (see Adjusting an Instrument's Temperature in Chapter 7).

2) Indicate that the temperature is set on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Checking for Errors

1) Ensure that no error codes are displayed on the Main screen.

2) Indicate that there are no errors on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Functional Testing

Modem Functional Test

1) Set the modem's DIP switches (see Figure 3-6).

2) When modem and telephone connections are available, connect the Modem Interface cable between the modem connector and the port labeled **Modem** (located on the bulkhead on the rear of the instrument).

Connect the telephone line (designated for modem access) into the **Jack** port of the modem. See Figure 3-5 for the bulkhead modem connection and Figure 3-6 for the 56K Fax Modem configuration diagrams.

3) Power up the modem. Have bioMérieux Support Services dial into the modem to verify the connection and modem's functionality.

Note: *US Robotics computer and jack modem ports are labeled on the bottom of the modem. (North America Only)*

4) Connect and configure the modems as shown in Figure 3-6. Set the modem dip switch (see Figure 3-6).

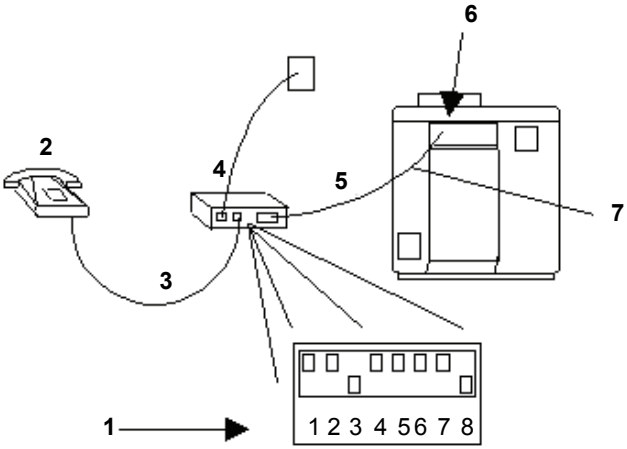

Figure 3-6: Modem Configuration and Dip Switch Settings

1 — Dip Switch settings are on the rear of the modem.
2 — Telephone
3 — Telephone Line
4 — Telco Modem
5 — Comp
6 — Modem Port Connection
7 — 957-0004-305 25-Pin to 9-Pin Cable

5) Indicate that the Modem Functional Test is complete on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Barcode Reader Functional Test

1) From the Main screen (see Figure 4-1), click the **Load Bottle** button.

The Load Bottle screen appears.

2) Scan a bottle and verify that the scanned number matches the bottle.

3) Press the **Done** button to exit the Load Bottle mode and return to the Main screen.

4) Indicate that Barcode Reader Functional Test is complete on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

UPS Functional Test (BacT/ALERT® 3D 60 Only, APC UPS 650)

1) Set the time to current local time.

2) Disable the audible alarms using the system software (see Setting the Audible Alarms in Chapter 6).

3) Remove AC power from the UPS by removing the UPS AC power cord from the wall outlet. Leave the UPS connected to the instrument and leave the power switch set to ON.

4) While waiting for 1 minute, verify that the UPS emits an audible alarm.

5) Verify that the blue Abnormal Shutdown screen appears on the instrument monitor screen.

6) Verify that the instrument powers down.

7) After the instrument powers off, restore power to the UPS.

8) Verify that the instrument retains the correct time and has no visible errors displayed on the monitor screen.

9) Indicate that the UPS Functional Test is complete on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

Installing the Optional Restraint

The countertop mounting hardware consists of screws and flat washers used to attach the instrument to a countertop (see Figure 3-7) or other surface of variable thickness. For a list of required parts, see Table 3-2.

Table 3-2: Restraint Hardware

Item	Quantity
¼ in. x 20 x 5 in. Bolt	4 each
¼ in. Flat Washer	4 each

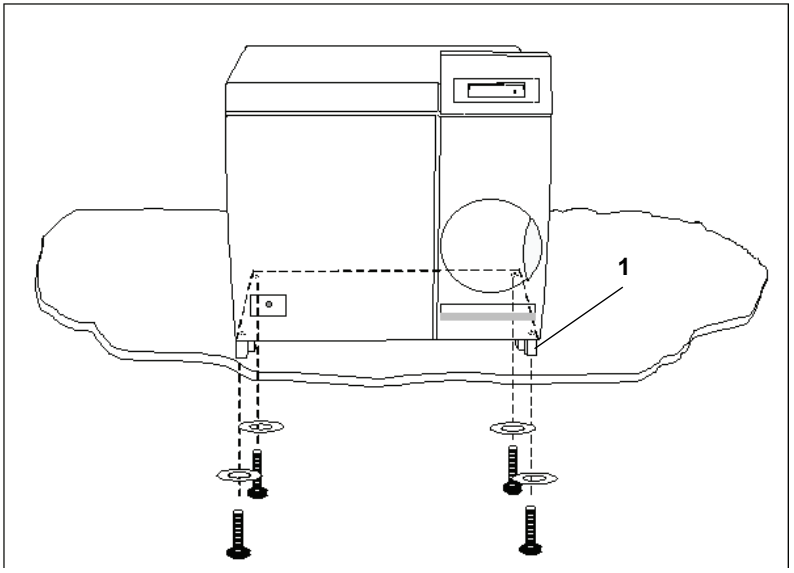

Figure 3-7: Countertop/Surface Mounting Diagram

1 – Threaded holes are accessible once the four rubber feet are removed.

1) Determine the desired location of the instrument on the countertop or mounting surface.

Note: *Care should be taken to avoid braces or bulkheads within the counter which could interfere with hardware installation and mounting. Drilling into these braces may reduce the integrity of the counter's strength.*

2) Determine the length of the bolts needed for mounting (see Figure 3-8).

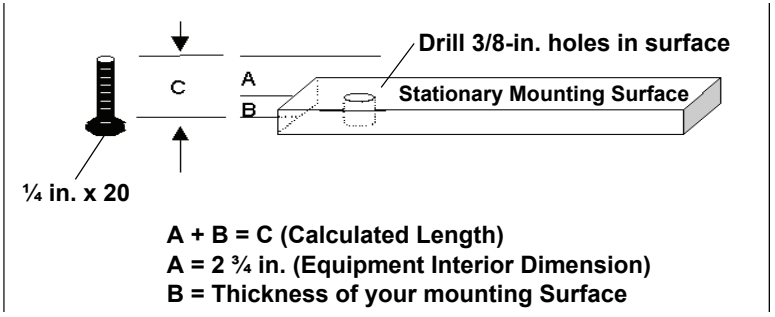
Drill 3/8-in. holes in surface
C
A
B
Stationary Mounting Surface
¼ in. x 20
A + B = C (Calculated Length)
A = 2 ¾ in. (Equipment Interior Dimension)
B = Thickness of your mounting Surface

Figure 3-8: Mounting Surface Diagram

For mounting surfaces up to 2 ¼ in. thick, use the 5-in. bolts supplied with the instrument. For mounting surfaces or surfaces requiring longer bolts, use Table 3-3 and Figure 3-8 to determine the required bolt length.

Table 3-3: Table of Equivalent Dimensions (Inches to Centimeters)

Equivalent Dimensions	
½ in. = 1.3 cm	4 in. = 10.2 cm
2 ½ in. = 6.4 cm	5 in. = 12.7 cm
2 ¾ in. = 7 cm	13 in. = 33 cm
3 ½ in. = 8.9 cm	21 in. = 53 cm

3) Transfer the dimensions from the Mounting Surface (Drilling) Template (see Figure 3-9) to the actual mounting surface.

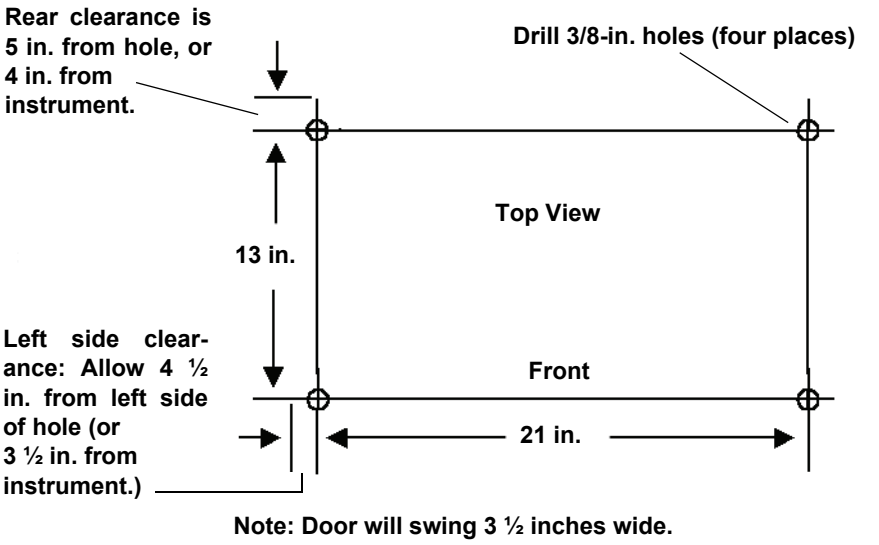
Rear clearance is 5 in. from hole, or 4 in. from instrument.
Drill 3/8-in. holes (four places)
Top View
13 in.
Left side clearance: Allow 4 ½ in. from left side of hole (or 3 ½ in. from instrument.)
Front
21 in.
Note: Door will swing 3 ½ inches wide.

Figure 3-9: Mounting Surface (Drilling) Template

4) Properly locate and drill four 3/8-in. diameter holes in the mounting surface.

5) Remove the rubber feet from the instrument.

- Position the instrument. Insert the bolts through ¼-in. flat washers, through the mounting surface, and into the threaded inserts of the instrument (see Figure 3-9).

6) Lightly tighten the bolts.

Note: *Over-tightening the bolts may loosen the threaded inserts.*

7) Indicate that the optional restraint is installed on the BacT/ALERT® 3D 60 Installation Checklist in Appendix C.

BASIC FUNCTIONS 4

About This Chapter

This chapter introduces you to the Main screen and provides you with procedures on how to perform daily basic functions.

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Manually Entering Text into a Data Entry Field (Keyboard) • 4-9

Loading Bottles • 4-10

Loading Bottles • 4-10

Changing the Maximum Test Time (Individual Bottles) • 4-13

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Unloading Bottles • 4-15

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Introduction

The basic functions are those tasks that may be performed during daily workflow. They include:

- Monitoring the system
- Entering order information (where applicable)
- Loading and unloading bottles
- Viewing and printing data
- LIS interaction with the BacT/ALERT® 3D SelectLink
- Accessing the Setup screen

Monitoring the System

Main Screen Introduction

The BacT/ALERT® 3D 60 system can be monitored from the Main screen (see Figure 4-1).

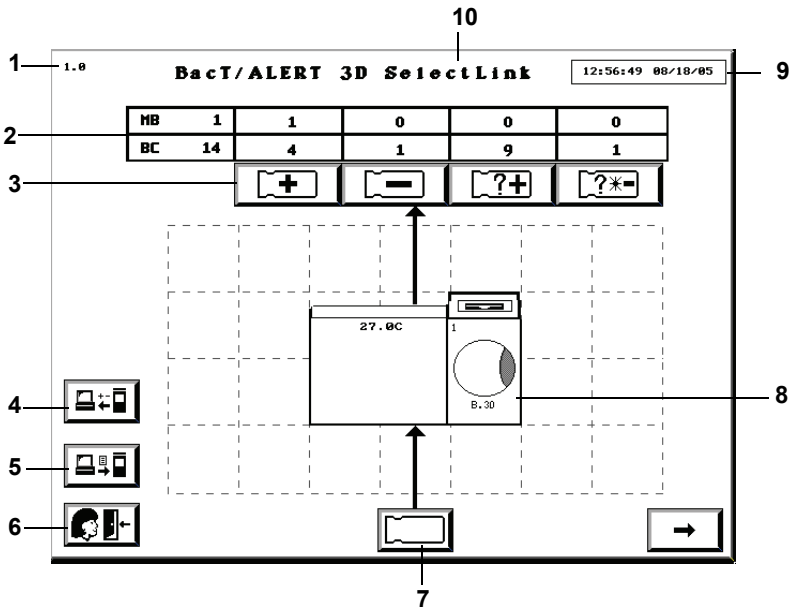


Figure 4-1: Main Screen

1 — Screen ID Number

2 — Bottle Count Table

3 — Unload Buttons

4 — Manual Send Test Results button (SelectLink only)

5 — Manual Request Test Orders button (SelectLink only)

6 — Logout button (21 CFR Part 11 mode only)

7 — Load Bottles button

8 — Instrument Icon

9 — Current Date/Time

10 — Software Configuration

CAUTION: If the current date/time displayed at the top of the screen does not advance, call bioMérieux Customer Service immediately.

Background Color

The default background color is determined by the software configuration (see Software Configuration Options in Chapter 2). The following conditions will override default background colors:

- A yellow screen indicates that the instrument has detected a positive bottle.

- A red screen indicates that an instrument fault has occurred. Clicking anywhere on the screen or pressing any key on the keyboard returns a red screen to yellow, or the configuration default color, depending on whether positive bottles are present. The fault code will remain on the screen until the error is corrected.

Instrument Icon

The following information is indicated on the **Instrument** icon:

- System ID numbers are assigned to both the Instrument and the Incubation Chamber.
- The programmed optimal temperature (ºC) is displayed for the Incubation Chamber.
- Software version number for the BacT/ALERT® 3D 60.
- Disabled or uninstalled components appear diagonally striped in gray on the screen.

Note: *An entire rack will appear diagonally striped if only one of its cells is disabled.*

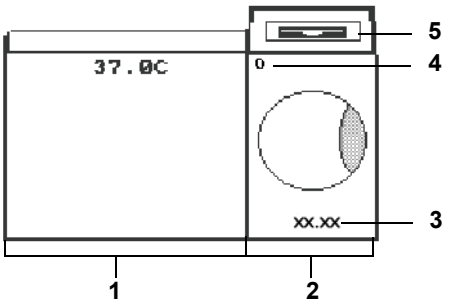


Figure 4-2: Instrument Icons

1 — Incubation Chamber
2 — Instrument
3 — Software Version
4 — Controller ID
5 — Backup Drive

Bottle Count Table

Located just above the **Instrument** icon are the **Unload** buttons and a table indicating the number of bottles of each type currently loaded in the instrument.

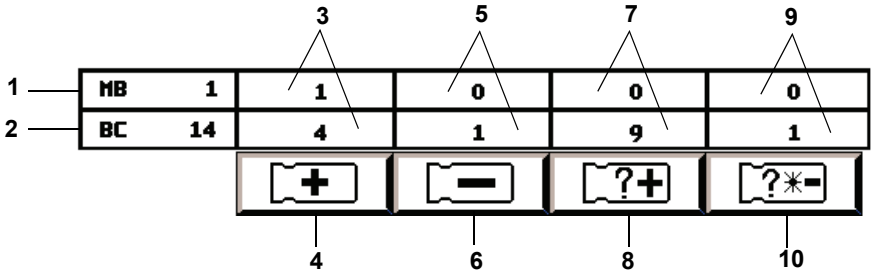


Figure 4-3: Bottle Count Table/Unload Buttons

1 — Total number of mycobacteria (MB) bottles loaded in the system.

2 — Total number of blood or sterile fluid culture (BC) bottles loaded in the system.

3 — Total number of identified bottles with a positive test status.

4 — Unload Positive Identified Bottles Button

5 — Total number of bottles (identified and anonymous) with a negative test status.

6 — Unload Negative Bottles Button

7 — Total number of anonymous bottles with a positive test status.

8 — Unload Positive Anonymous Bottles Button

9 — Total number of anonymous bottles with a negative-to-date or negative test status.

10 — Unload Anonymous Negative or Negative-to-Date Bottles Button

Viewing Faults

Instrument faults are reported using a numeric code within a diamond shape. Fault codes are displayed on the **Instrument** icon where the fault condition exists.

Note: *Only high priority codes are displayed on the Instrument icon.*

1) If the code appears on the Instrument or the right side of the icon, then move to Step 4. If the fault code appears on an Incubation Chamber or left side of the icon, then continue to Step 2.

2) Click the Incubation Chamber on the **Instrument** icon.

3) The View Cell Status screen appears (see Figure 4-4, View Cell Status Screen, on page 4-6).

- Door faults appear at the top of the screen.
- Rack faults appear at the left end of the rack display.
- Cell faults appear in the cell display.

4) For a complete list and description of Instrument Fault Codes, see the topic, Instrument Fault Codes in Chapter 8.

Viewing the Cell Status Screen

The View Cell Status screen is continuously updated with changes that occur while the screen is active, such as the loading/unloading of bottles, new test results, and the error status as indicated by fault codes appearing or disappearing. To view the cell status screen:

1) Display the View Cell Status screen by clicking the appropriate Incubation Chamber on the left side of the **Instrument** icon (see Figure 4-1, Main Screen).

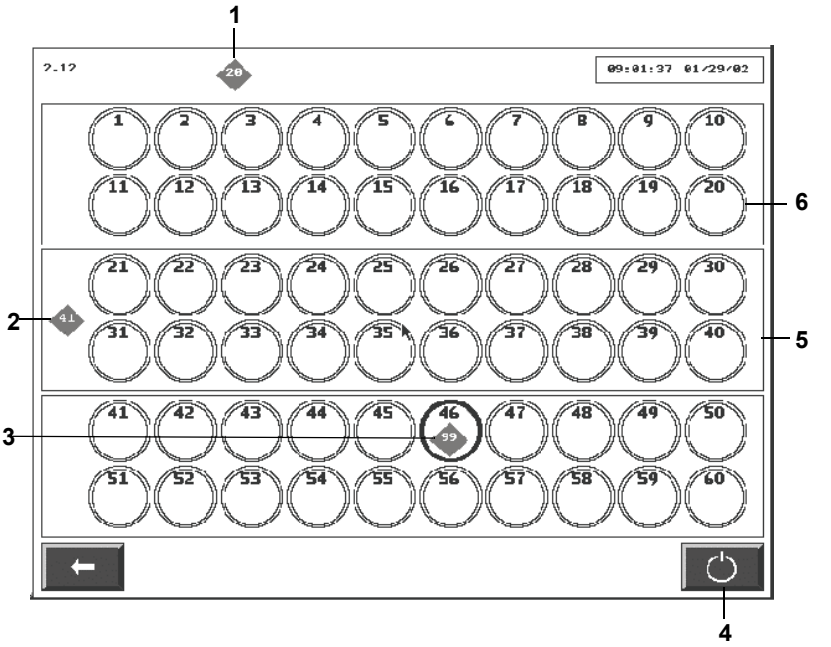


Figure 4-4: View Cell Status Screen

1 — Door Fault Code
2 — Rack Fault Code
3 — Cell Fault Code
4 — Restart Incubation Chamber Button
5 — Rack
6 — Cell Button

2) Click the **Previous Screen** button to return to the Main screen.

Understanding the View Cell Status Screen Display

For each cell, the cell identification number appears at the top of the circle.

A hollow circle indicates an empty cell, and a solid circle indicates a loaded cell. The color of the solid circle indicates the bottle status or a cell that is pending quality control check.

- Black — negative-to-date bottle
- Green — negative bottle
- Yellow — positive bottle
- White — cell is pending quality control check

Loaded cells also contain symbols to indicate the bottle status:

+	Positive
–	Negative
*	Negative-to-date
~ +	Critical determination in progress. (Represents a bottle that is presently undergoing a critical determination as to whether it will turn positive or remain negative or negative-to-date.)

Note: *Bottles with a critical determination in progress status will be temporarily removed from the bottle count table on the Main screen.*

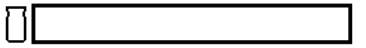
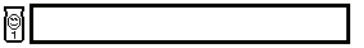
Cells loaded with an anonymous bottle contain a **?**. If a loaded cell contains no **?**, then the bottle is identified.

Disabled racks and cells are indicated by gray diagonal stripes (see Figure 4-5) within their borders. (see Enabling and Disabling Racks and Cells in Chapter 7).

Figure 4-5: Disabled Cell

Text/Data Entry

Common Text Fields and Field Limits

	**Bottle ID** field
	**Patient First Name** field — may contain up to 20 characters
	Patient Last Name field — may contain up to 31 characters
	Accession Number field — may contain up to 16 characters
	Hospital ID field — may contain up to 22 characters

Note: *The field length and initial character type (alpha, numeric, or other) can be configured for the **Accession Number** field. The initial character type can be configured for the **Bottle ID** field. To configure these fields, contact your local bioMérieux Representative.*

Note: *The fields may manually be made unavailable or disabled regardless of software configuration. To make the field(s) unavailable or disabled, call your local bioMérieux Representative.*

Using the Barcode Scanner to Enter Data

To scan a bottle or accession barcode:

1) Before scanning the barcode, click the desired field to place focus on that field. The field should turn white indicating focus.

2) Rotate the bottle so the bottle ID or accession number barcode is on top.

3) Place the bottle over the barcode strip located at the base of the barcode reader stand (see Figure 2-2, Instrument Front View).

4) There will be two short beeps when the bottle ID is successfully scanned into the **Bottle ID** field.

5) If the **Accession Number** field is enabled, there will be three short beeps when the accession number is successfully scanned into the **Accession Number** field.

If an Operator Error occurs, a series of beeps will alert the operator to view the Monitor.

If the barcode is not read:

1) Verify the appropriate field has focus.

2) Move the bottle away from the barcode strip and initiate another scan.

Note: *The **Hospital ID** field is a keyboard-entry field only.*

Manually Entering Text into a Data Entry Field (Keyboard)

Field text, where applicable, can be entered using the keyboard. If a barcode label cannot be scanned successfully, the bottle ID or accession number can also be entered using the keyboard.

See Appendix D for International character entry instructions.

Note: *Before entering text into a field, touch the desired field to place focus on that field. The field should turn white indicating focus.*

1) Using the keyboard, enter the desired text.

2) Press the **Tab** key to move focus to the next field.

Note: *If desired, change the cursor location using the keyboard keys. Keys that provide cursor positioning and editing functions are as follows:*

LEFT ARROW	Moves cursor left one position
RIGHT ARROW	Moves cursor right one position
HOME	Moves cursor to the start of the text field
END	Moves cursor to one position past end of text
DELETE	Deletes the character at the current cursor position
BACKSPACE	Deletes the character at the current cursor position and moves the cursor left one position

Note: *Entering text does not over-write existing text located to the right of the insertion point.*

Note: *Entered text defaults to all-uppercase. To change the default, contact your local bioMérieux Representative.*

Loading Bottles

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. Completely load a bottle according to this procedure before proceeding to the next bottle.

Loading Bottles

1) From the Main screen (see Figure 4-1), click the **Load Bottles** button ( ).

The Load Mode screen appears.

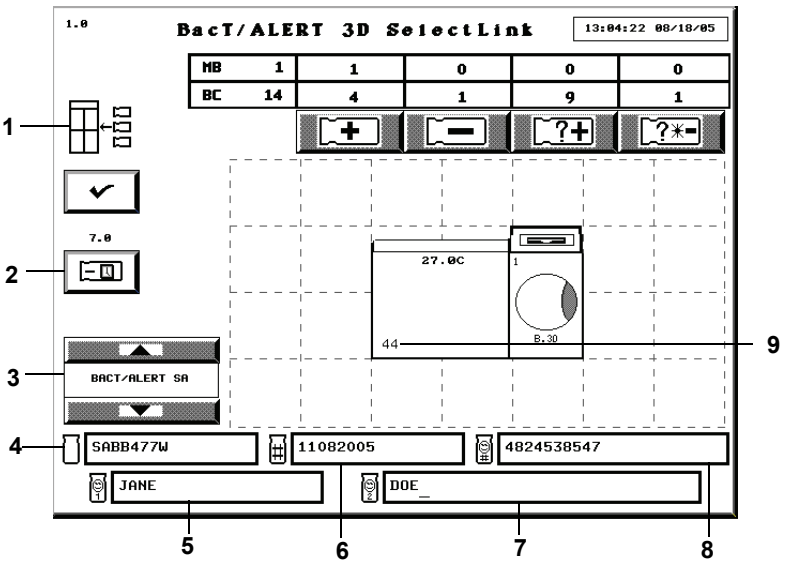


Figure 4-6: Main Screen — Load Mode

1 — Load Bottles Icon
2 — Change Maximum Test Time Button
3 — Bottle Type Scroll Button
4 — Bottle ID Field
5 — Patient First Name Field
6 — Accession Number Field
7 — Patient Last Name Field
8 — Hospital ID Field
9 — Cells Available for Loading

The number of available cells appears at the bottom left hand side of the **Instrument** icon.

CAUTION: Inspect each bottle and sensor before loading.

If the sensor is yellow, treat the bottle as positive. If the bottle is cracked, do not load the bottle.

2) Verify the **Bottle ID** field appears white, then scan or manually enter the bottle ID (see Text/Data Entry on page 4-8).

If the field is left blank when a bottle is loaded, then the bottle is considered anonymously loaded (see Handling Anonymous Bottles on page 4-14).

3) Verify the correct bottle type is displayed on the **Bottle Type** scroll button.

If the **Bottle ID** field contains data from a generic label, the bottle type can be manually entered using the **Bottle Type** scroll button before inserting the bottle to ensure proper testing of the bottle. The instrument will also beep continuously to alert the operator that the bottle type needs to be manually entered. The audible alert can be disabled by calling bioMérieux for assistance. See Figure 4-6, Main Screen — Load Mode, on page 4-10.

CAUTION: For best results, manually enter the bottle type when "GENERIC" is the displayed bottle type. Otherwise, observe the following:

The maximum test time assigned to a generic bottle loaded into an incubation chamber configured for MB is the same time assigned to the BacT/ALERT® MP media type in the Set Maximum Test Type screen (see Setting the Maximum Test Time in Chapter 6).

All non-MB bottles loaded into an Incubation Chamber for BC have a maximum test time set to the time specified for the Unknown bottle type.

BacT/ALERT® MB Bottles should never be loaded with a Generic media type or loaded anonymously. BacT/ALERT® MB must be displayed on the Bottle Type scroll button before loading a BacT/ALERT® MB bottle.

4) If the **Accession Number** field is enabled and blank, then continue to Step 5. If the **Accession Number** field is disabled, then go to Step 7.

5) Verify the **Accession Number** field appears white, then scan or manually enter the *accession number*.

6) If the fields are displayed and enabled, then manually enter the following in the order listed: *Hospital ID*, *Patient First Name*, and *Patient Last Name*.

- Entries to the **Patient First Name** and **Patient Last Name** fields cannot be made without the *Hospital ID* entry.
- To change the order of the patient name fields, contact your bioMérieux Representative.

Note: *The **Hospital ID** field is a keyboard-entry only field.*

7) The default maximum test time is displayed above the **Change Maximum Test Time** button. The scanned bottle's maximum test time can be adjusted if desired. See Changing the Maximum Test Time (Individual Bottles) on page 4-13.

8) Open the Incubation Chamber door. Available cells will have an illuminated cell indicator light.

9) Insert the bottle, sensor first, into a cell with an illuminated cell indicator light.

WARNING

An erroneous test result (ex. false negative or false positive) could occur if a bottle is not fully seated into a cell. When inserting a bottle, ensure the bottle is fully seated into the cell.

10) The cell indicator light blinks slowly to acknowledge the bottle is loaded.

11) Verify that all text fields clear before proceeding.

12) Repeat Step 2 through Step 11 for each remaining bottle. Limit the bottle load time to two minutes in one area to control entry of room temperature bottles into racks. Close the door to allow temperature to equilibrate before loading in that area again.

CAUTION: If a large number of bottles are loaded into the Incubation Chamber at the same time and in the same areas, a large heat mass loss within the racks may occur. This heat loss may trigger the acceleration or rate algorithms to erroneously flag positive.

13) When all bottles are loaded, ensure that the doors are completely closed, then click the **Check** button.

If no operator or bottle loading activity has been recorded in a period of two minutes, the instrument will terminate the Load Bottle operation. Operator activity includes:

- pressing keys on the keyboard
- scanning barcodes
- moving the mouse
- loading or unloading bottles

Changing the Maximum Test Time (Individual Bottles)

1) From the Load screen, click the **Change Maximum Test Time** button ( ) after scanning the bottle barcode.

The Change Maximum Test Time screen overlays and disables the Load screen.

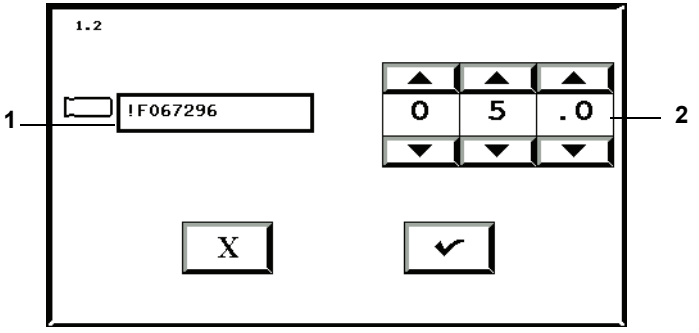


Figure 4-7: Change Maximum Test Time Screen

1 — Bottle ID Field

2 — Max Test Time Scroll Buttons

2) Verify the bottle ID matches that of the bottle for which you wish to change the maximum test time.

3) Adjust the maximum test time in days using the **Max Test Time** scroll buttons.

4) Click the **Check** button to accept the changes, or the **Cancel** button to retain the original setting.

The system returns to the Load Mode screen.

Note: *Changing the maximum test time of an individual bottle during loading does not affect any other bottles of the same type.*

Note: *The maximum test time of an individual bottle can also be changed from the Edit Bottle Detail screen (see Viewing/Editing Bottle Data in Chapter 5) after loading.*

Handling Anonymous Bottles

Bottles loaded into the Incubation Chamber without accessing the Load Bottles function on the Main screen are referred to as Anonymous bottles because they are not associated with a bottle ID.

CAUTION: BacT/ALERT® MB (Mycobacteria Blood) Bottles should never be loaded anonymously. Appropriate testing of anonymous bottles occurs only when BacT/ALERT® MP bottles are loaded into an Incubation Chamber configured for MB.

The maximum test time of anonymous bottles loaded into the MB Chamber is the same time specified for the BacT/ALERT® MP media type on the Set Maximum Test Time screen.

Anonymous bottles loaded into the BC chamber are assigned the standard default algorithm.

Anonymous bottles should be either removed and identified as specified in Unloading Bottles on page 4-15 or identified using the Edit Bottle Detail screen (see Editing Bottle Details Using the Edit Bottle Detail Screen in Chapter 5).

Unloading Bottles

The BacT/ALERT® 3D 60 signals which type of bottles are ready for unloading by enabling the appropriate **Unload** button.

CAUTION: In order to preserve test data integrity, handle only one bottle at a time. It is important to complete the procedure for each bottle before proceeding to the next bottle.

Unloading Bottles

1) Generate an Unload report (see Viewing and Printing Test Data on page 4-22).

2) From the Main screen (see Figure 4-1), click the appropriate **Unload** button.

The Unload Mode screen appears.

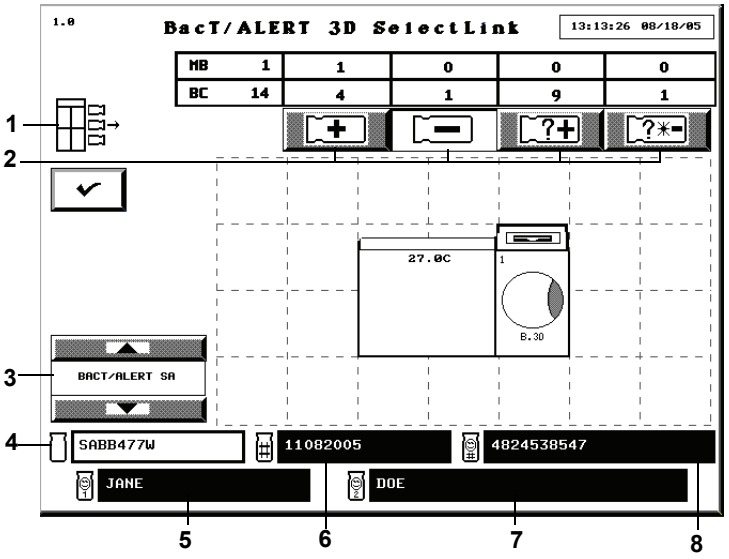


Figure 4-8: Main Screen — Unload Mode

1 — Unload Bottles Icon
2 — Unload Buttons
3 — Bottle Type Scroll Button
4 — Bottle ID Field
5 — Patient First Name Field
6 — Accession Number Field
7 — Patient Last Name Field
8 — Hospital ID Field

3) Open the door. When the door is open, the cell indicator lights will light next to all bottles in the selected category.

4) Remove one of the bottles indicated. Wait for the cell indicator light to blink slowly to acknowledge the removal of the bottle.

5) If the bottle was identified when loaded:

a. The bottle ID and the bottle type will appear on the Unload Mode screen; however, the accession number, hospital ID, patient first name and patient last name will appear in disabled text fields, if information is available.

b. It is not necessary to re-scan the bottle ID; however, doing so will verify that bottle's identity.

c. If fields are blank or need editing, then use the Edit Data Relationships function (see Editing Data Relationships in Chapter 5).

6) If the bottle was anonymously loaded (the **Bottle ID** field is blank), scan or manually enter the bottle ID.

a. Identify the bottle by entering the bottle ID, bottle type, accession number, hospital ID, and patient first and last name (see Loading Bottles on page 4-10).

- Scanning the bottle ID successfully results in two short beeps.
- Scanning the accession number successfully results in three short beeps.
- When identifying anonymous bottles, information entered in the **Bottle ID**, **Bottle Type**, **Accession Number**, **Hospital ID**, **Patient First Name** and **Patient Last Name** fields is associated with the unloaded bottle once the next bottle is unloaded or the **Check** button is clicked.

b. If the bottle is to be reloaded, immediately return the bottle to the cell with the slowly blinking cell indicator light before unloading another bottle.

WARNING

Bottles with a critical determination in progress will be temporarily removed from the bottle count table on the Main screen.

Note: *Do not reload the anonymous bottle if its status is negative or positive.*

CAUTION: Reloading bottles anonymously that were previously loaded will result in duplicate bottle records.

7) Repeat Step 3 through Step 7 for the remaining bottles to be unloaded. Limit the bottle unload time to no more than two minutes in one area.

Close the door to allow temperature to equilibrate before unloading from the area again.

CAUTION: If a large number of bottles are unloaded from the Incubation Chamber at the same time and in the same areas, a large heat mass loss within the racks may occur. This heat loss may trigger the acceleration or rate algorithms to erroneously flag positive.

8) When finished unloading bottles, ensure that the door is completely closed.

9) Click the **Check** button on the Unload Mode screen.

10) Verify that the bottles to be unloaded are listed on the Unload report.

11) Reload any previously Anonymous Negative-to-Date bottles.

If no operator or bottle loading activity has been recorded in a period of 2 minutes, the instrument will terminate the Unload Bottle operation. Operator activity includes:

- pressing keys on the keyboard
- scanning barcodes
- moving the mouse
- loading or unloading bottles

Handling Unconfirmed Positive Bottles (False Positives)

If a smear of a positive bottle reveals no microorganisms, the bottle should be subcultured and reloaded into the instrument via the Load Bottles function (see Loading Bottles on page 4-10).

Note: *If a bottle is reloaded into the instrument, its status will revert to negative-to-date once a reading has been taken (maximum time – ten minutes).*

If growth appears on the subculture, edit the bottle's status to Positive on the Edit Test Result screen which is accessed from the Edit Bottle Detail screen (see Edit Test Result Button in Chapter 5), and unload the now positive bottle.

Note: *Results that have been manually changed to negative or positive via the Edit Bottle Detail screen (see Editing Bottle Details Using the Edit Bottle Detail Screen in Chapter 5) will be marked on the report with a stick figure (웃).*

Note: *If a bottle is positive (set manually, or positive by any other reason) and then is manually changed to negative-to-date, the stick figure (웃) will not appear.*

Accessing the Setup Screen Function Buttons

To view and print data, print graphs, and perform all of the editing, configuration, and maintenance functions of the system, you must first access the Setup screen function buttons.

Accessing the Setup Screen

1) From the Main screen (see Figure 4-1), click the **Next Screen** button ( ).

The Setup screen appears.

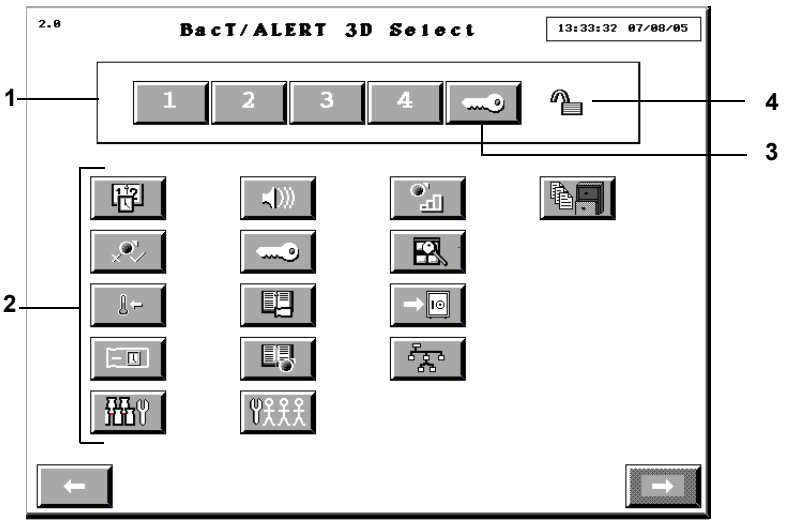


Figure 4-9: Setup Screen

1 — Password Entry Keypad
2 — Function Buttons
3 — Key Symbol Button
4 — Padlock Icon

2) Enter a valid password using the **1** – **4** buttons. Until a valid password is entered and accepted, the **Padlock** icon will appear in the closed position.

Note: *Acceptable passwords consist of any combination of the numbers 1 to 4 and have a maximum length of eight characters.*

Note: *Instruments are shipped with a password of 1234. For information on changing the default password, see Changing the System Password in Chapter 6.*

3) Click the **Key Symbol** button to accept the password.

4) After a valid password is accepted, the **Padlock** icon changes to the full open position and the function buttons become enabled.

Note: *To correct an error made while entering a password, click the **Key Symbol** button and re-enter the password.*

Note: *If more than 8 characters are entered, the **Password Entry** buttons will become inactive and turn gray. Click the **Key Symbol** button and re-enter the password.*

Inactivity Timeout for all Setup Screens

While you are in the Setup screen (see Figure 4-9), or one of its sub-menus, an inactivity timeout will occur (within a period of time configured by your bioMérieux Service Representative) if you do not perform one of the following actions:

- press a screen or keyboard button
- scan a barcode
- load or unload a bottle

If an inactivity timeout occurs, the instrument display reverts from the currently displayed screen to the Main screen. Any pending function is cancelled as if the **Cancel** button on each successive screen was clicked.

Note: *If a timeout occurs, it is possible that partially entered information will be lost.*

Note: *The inactivity timeout feature is disabled while a red operator error is displayed on the screen.*

Setup Screen Function Buttons

Set Date/Time button (see Setting and Formatting the System Date and Time in Chapter 7)

Enable/Disable Rack, or **Cell** button (see Enabling and Disabling Racks and Cells in Chapter 7)

Calibrate Temperature button (see Checking an Instrument's Temperature in Chapter 7)

Set Maximum Test Time button (see Setting the Maximum Test Time in Chapter 6)

Set Audible Alarm Options button (see Setting the Audible Alarms in Chapter 6)

Change Password button (see Changing the System Password in Chapter 6)

Select Bottle to Edit/Graph button (see Selecting Bottles Using the Select Bottle to Edit/Graph Button in Chapter 5)

Edit Cell Contents button (see Editing Bottle Details Using the Edit Bottle Detail Screen in Chapter 5)

Calibrate Cell button (see Viewing a Cell's Readings and/or Calibrating a Cell in Chapter 7)

View Incubation Chamber Information button (see Viewing Incubation Chamber Information in Chapter 7)

Backup Management button (see Initiating Manual Backup in Chapter 6)

Edit Data Relationships button (see Initiating the Edit Data Relationships Function in Chapter 5)

Report button (see Viewing and Printing Test Data in Chapter 4)

Configure Users button — Button only appears in 21 CFR Part 11 Mode (see Configuring Users — 21 CFR Part 11 Mode in Chapter 9)

Bottle Processing/Customization button (For use only with instruction from bioMérieux)

Viewing and Printing

Introduction

Viewing Bottle Data

The following bottle information can be viewed by accessing the Edit Bottle Detail screen as described in Editing Test Data (see Viewing/Editing Bottle Data in Chapter 5):

- Bottle ID
- Accession number
- Hospital ID (where applicable)
- Patient first and last name (where applicable)
- Cell ID
- Maximum test time
- Bottle type
- Date/time loaded
- Date/time unloaded
- Date/time of last bottle reading
- Test time
- Test result
- Algorithm type
- How determined/positivity index

Viewing/Printing Reports

Reports are viewed and printed by using the **Report** button as described in the topic, Viewing and Printing Test Data on page 4-22.

Viewing/Printing Graphs

Bottle Graphs can be viewed on the BacT/ALERT® 3D 60 as described in the topic, Viewing and Printing Bottle Graphs on page 4-29.

Note: *The print feature can be made unavailable. When the feature is unavailable, the **Print** buttons do not display. To make the print feature unavailable, call your local bioMérieux Representative.*

Using the Print Screen Function

You can print the current screen on the instrument by pressing **Ctrl** + **P** on the keyboard.

Viewing and Printing Test Data

1) From the Setup screen (see Figure 4-9), click the **Report** button ( ).

The Report Selection screen appears.

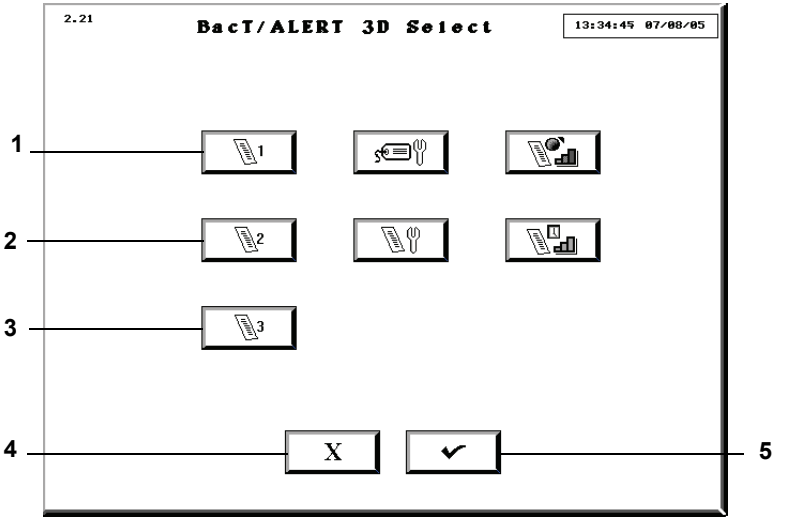


Figure 4-10: Report Selection Screen

1 — Display Report 1 Button
2 — Display Report 2 Button
3 — Display Report 3 Button
4 — Previous Screen Button
5 — Check Button

2) Click the **Display Report 1**, **2**, or **3** button that is configured for the information desired.

The Report screen will display. There are three default report configurations:

- **Display Report 1** button — Generates the Load Report screen with **1st Load Time** as the primary sort, and **Accession Number** as the secondary sort. Report has section breaks based on **1st Load Time**.
- **Display Report 2** button — Generates the Status Report screen with **Accession Number** as the primary sort, and **Bottle Type** as the secondary sort. Report has section breaks based on **Accession Number**.

- **Display Report 3** button — Generates the Unload Report screen with **Loaded** as the primary sort, and **Test Result** as the secondary sort. Report has section breaks based on **Loaded** and **Test Result**.
- See Configuring Report Contents in Chapter 6 for examples of the Load, Status and Unload Report Configuration screens.

Note: *Data from the last 1,920 bottles are displayed each time a Report screen is accessed. The report screens come configured with default settings, but the report configurations can be changed to display different data and to sort the data differently (see Configuring Report Contents in Chapter 6).*

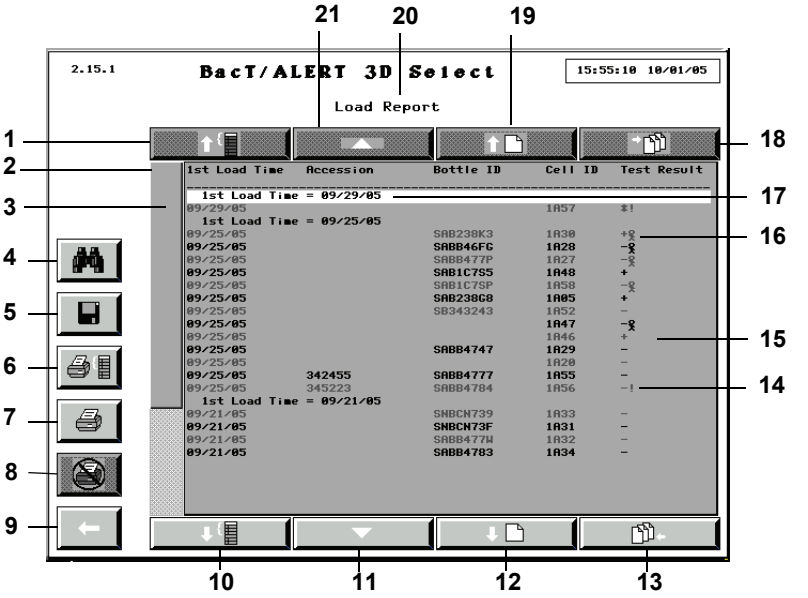


Figure 4-11: Sample Report Screen

1 — Section Scroll Up Button
2 — Relative Record Scroll Indicator
3 — Relative Record Scroll Bar
4 — Find Text Button
5 — Save Button
6 — Print Current Section Button
7 — Print Report Button
8 — Cancel Print Button
9 — Previous Screen Button
10 — Section Scroll Down Button
11 — Line Scroll Down Button
12 — Page Scroll Down Button
13 — End Scroll Button
14 — Gap Detection Indicator
15 — Report Data Lines
16 — Stick Figure
17 — Current Section Line
18 — Home Scroll Button
19 — Page Scroll Up Button
20 — Report Title
21 — Line Scroll Up Button

Note: *Results that have been manually changed (see Editing Bottle Details Using the Edit Bottle Detail Screen in Chapter 5) will be marked on the report with a stick figure (🯅).*

Note: *If a bottle is positive (set manually, or positive by any other reason) and then is manually changed to negative-to-date, the stick figure (🯅) will not appear.*

Note: *Bottles with an Instrument Fault Code 80 will be marked on the report with a **Gap Detection** indicator (**!**) next to the result. If a negative bottle has an*

*Instrument Fault Code 80 while it is being unloaded, the **Gap Detection** indicator will remain on the report (see Instrument Fault Codes in Chapter 8).*

Note: *The Current Section Line will always display the section that is associated with the first displayed data record. It is always highlighted for easy reference. If there are no section breaks in the displayed report, this line will become the first line of data records displayed and reference highlighting will not occur.*

3) To scroll up or down a section, click the appropriate **Section** scroll button.

Note: *The **Section** scroll buttons are disabled if there are no section breaks in the displayed report or if there are no available sections in the indicated direction.*

4) To scroll up or down a data line, click the appropriate **Line** scroll button or press the appropriate ↑ or ↓ key on the keyboard.

Note: *The **Line** scroll buttons are disabled if there are no data lines in the indicated direction.*

5) To scroll up or down a data page, click the appropriate **Page** scroll button or press the appropriate **Page Up** or **Page Down** key on the keyboard.

Note: *The **Page** scroll buttons are disabled if there are no data lines in the indicated direction.*

6) To scroll up to the oldest data line (the first data record in the report), click the **Home** scroll button or click the **Home** key on the keyboard.

Note: *The **Home** scroll button is disabled if there are no report data lines in the indicated direction.*

7) To scroll down to the newest data line (the last data record in the report), click the **End** scroll button or click the **End** key on the keyboard.

Note: *The **End** scroll button is disabled if there are no report data lines in the indicated direction.*

8) To move to a relative record position, click the **Relative Record** scroll bar above/below the Relative Record Indicator.

Note: *The Relative Record Indicator is sized proportionally to the amount of records in the report.*

Note: *The **Relative Record** scroll bar is disabled if the Relative Record Indicator is the same size as the scroll bar and all the data records in the report are displayed.*

9) To print the report, click the appropriate **Print** button:

- Clicking the **Print Report** button prints all records in the database (with a maximum of 1,920 records).
- Clicking the **Print Current Section** button prints the Current Section Line and all data records associated with the section.

Note: *The **Print** buttons are only available if a printer is configured for the system. To configure a printer for the system, contact your local bioMérieux Representative.*

10) While the report is printing:

- All **Print** and **Save** buttons are disabled.
- The operator may, however, view and scroll through the displayed report, search for text in the displayed report, or exit the Report screen and perform other operations.
- The **Cancel Print** button becomes available.

11) Click the **Cancel Print** button to stop sending data to the printer and to empty the queue of any data waiting to be sent to the printer.

Note: *Once the cancellation has been completed, the **Print** and **Save** buttons will become enabled and the **Cancel Print** button will be disabled.*

12) To specify a text string and initiate a search of the report data for the specified text, click the **Find Text** button.

The Find Text screen appears.

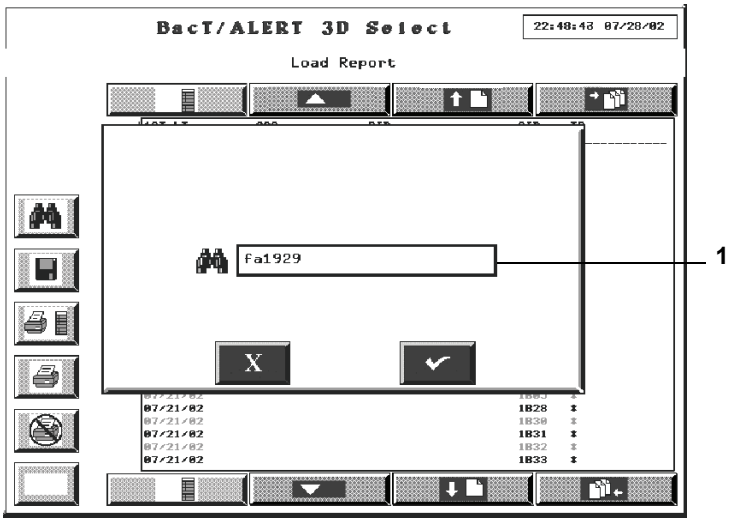


Figure 4-12: Find Text Screen

1 — Find Text Field

Enter desired text and click the **Check** button. The report screen is displayed. Clicking the **Cancel** button will cancel the search request and return to the Report screen.

Note: *The search will be performed upon returning to the Report screen starting from the top of the report. The record that contains the first occurrence of the text will be scrolled to the first line of data displayed and the text itself will be highlighted for reference.*

If no occurrence of the specified text is found, the data displayed will not change and no reference highlighting will occur.

13) To find the next instance of the specified text, press the **F3** key on the keyboard.

Note: *If no new instance of the text is found the data displayed and the highlighted text will remain the same.*

14) To save the displayed report to a text file, click the **Save** button.

The Save To File screen appears.

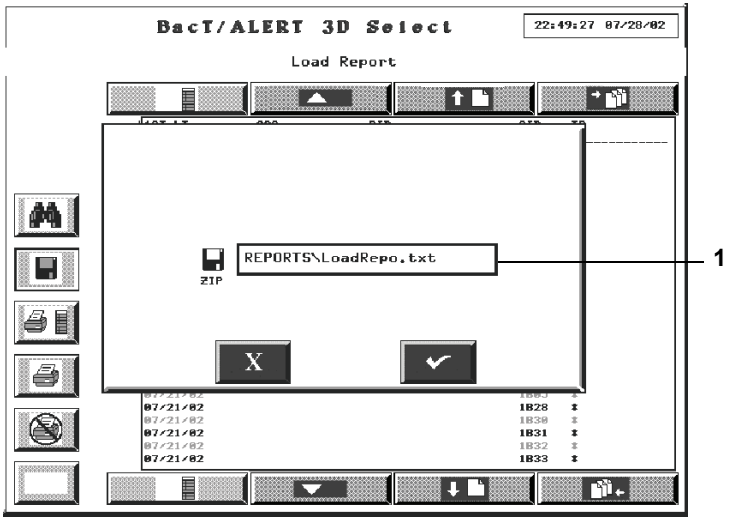


Figure 4-13: Save to File Screen

1 — File Name Field

Note: *The default file name and path will appear automatically in the **File Name** field. Use the keyboard to change the name of the file.*

Note: *All reports are saved to the pathname, **D:\REPORTS**, either using the default file name or a specified file name. All reports are automatically given an extension of **.TXT**.*

15) Place the backup media in the backup drive.

Note: *Backup media can either be a Zip® disk or a USB flash drive.*

16) Click the **Check** button to initiate the save and return to the report screen. Clicking the **Cancel** button will cancel the save request and return to the Report screen.

Note: *The **Print** buttons will be disabled while the save is taking place. Once the save has completed, the **Print** buttons will be enabled.*

WARNING

Do not insert any object, other than a Zip® disk, into the Zip® drive under any circumstances.

CAUTION: Do not forcibly remove the Zip® disk from the instrument. Forcibly removing the Zip® disk may cause damage to the Zip® disk or Zip® drive and may cause the system to lock up.

17) Click the **Previous Screen** button to return to the screen from which the Report screen was accessed.

Viewing and Printing Bottle Graphs

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons on page 4-18).

2) Click the **Select Bottle to Edit/Graph** button ( ).

The Select Bottle to Edit/Graph screen overlays and disables the Setup screen.

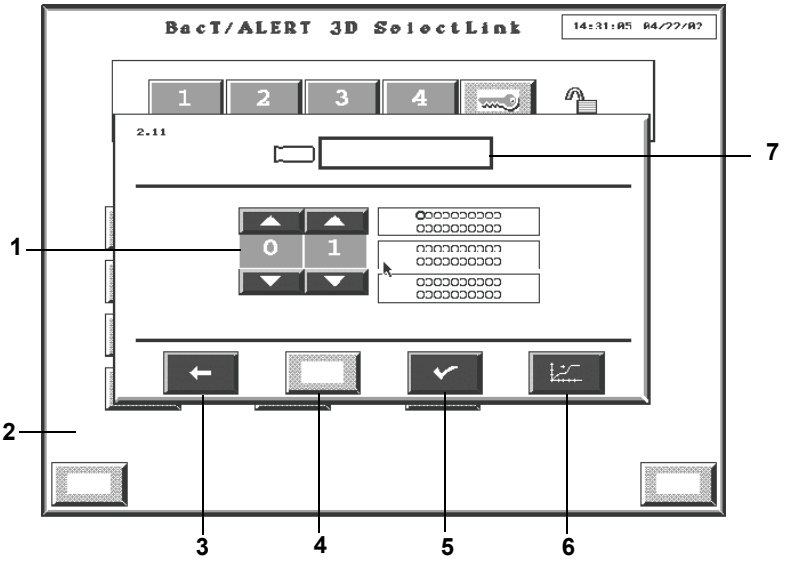


Figure 4-14: Select Bottle to Edit/Graph Screen

1 — Cell Scroll Buttons
2 — Setup Screen (Disabled)
3 — Previous Screen Button
4 — Cancel Button
5 — Check Button
6 — Graph Bottle Readings Button
7 — Bottle ID Field

3) If you know the bottle ID of the bottle whose readings you wish to graph, then enter the *bottle ID* in the **Bottle ID** field (see Text/Data Entry on

page 4-8) and go to Step 5. If you know the cell location but not bottle ID, then continue to Step 4.

Note: *Only the last 1,920 bottles loaded can be retrieved. Any other entry in the* ***Bottle ID*** *field is invalid and will cause an Operator Error 940 (see Operator Error Codes in Chapter 8).*

4) Adjust the **Cell** (1 – 60) scroll buttons to select the cell location of the bottle whose readings you wish to graph. The cell location defaults to Cell 1.

Note: *Only cell locations with currently loaded bottles can be used to view bottle graphs. To view graphs of recently unloaded bottles (the most recent 1,920 bottles loaded), you must use the* ***Bottle ID*** *field.*

5) Click the **Graph Bottle Readings** button ( ).

The Graph Bottle Readings screen appears.

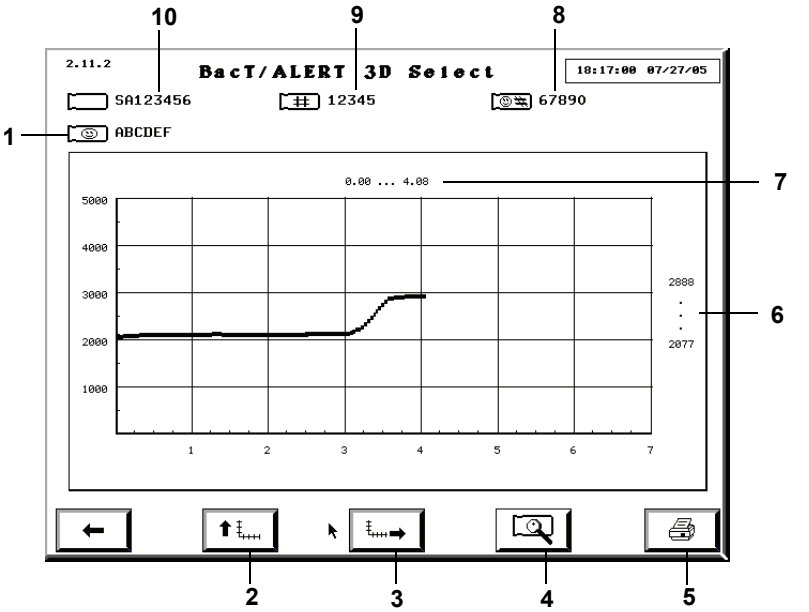


Figure 4-15: Graph Bottle Readings Screen

1 — Name Field
2 — Adjust Y Scale Button
3 — Adjust X Scale Button
4 — Bottle Readings Button
5 — Print Graph Button
6 — Bottle Readings Range
7 — Days Tested Range
8 — Hospital ID Field
9 — Accession Number Field
10 — Bottle ID Field

You can also access the Graph Bottle Readings screen via the Edit Bottle Detail screen (see Editing Bottle Details Using the Edit Bottle Detail Screen in Chapter 5). The screen ID number is the same regardless of how it is accessed.

- The Y axis range defaults to 0 – 5000, and the X axis range defaults to 0 – maximum test time of the bottle in days.
- If the bottle was determined positive, then a dot and the time to detection are displayed at the point where it was determined positive.

6) To adjust the Y or X axis, click the appropriate **Adjust Scale** button. When one of these buttons is clicked, the axis re-scales so that the maximum endpoint of the scale is just higher then the maximum value of the range. Adjusting the scale may mean increasing or decreasing the range of the scale.

When one of the **Adjust Scale** buttons is clicked, the arrow on the button changes directions. To return to the original scale, click the **Adjust Scale** button(s) a second time.

7) Click the **Print Graph** button, if available, to print the graph as it appears on the screen.

Note: *The **Print Graph** button is only available if a printer is configured for the system. The **Print Graph** button is disabled while a print is in progress.*

Note: *To configure a printer for the system, contact your local bioMérieux Representative.*

8) When done, click the **Previous Screen** button to return to the Select Bottle to Edit/Graph screen.

Display Bottle Readings

The Bottle Readings screen displays the exact values of the bottle readings for an individual bottle, along with the date and time each reading was taken.

Note: *The polynomial is applied to the bottle readings. The readings are not the raw readings.*

If there are bottle readings available for you to view, the **Bottle Readings** button on the Graph Bottle Readings screen turns blue (see Figure 4-15). If there are no readings available, the button is gray.

1) From the Graph Bottle Readings screen (see Figure 4-15, Graph Bottle Readings Screen, on page 4-30), click the **Bottle Readings** button ( ).

The Bottle Readings screen appears.

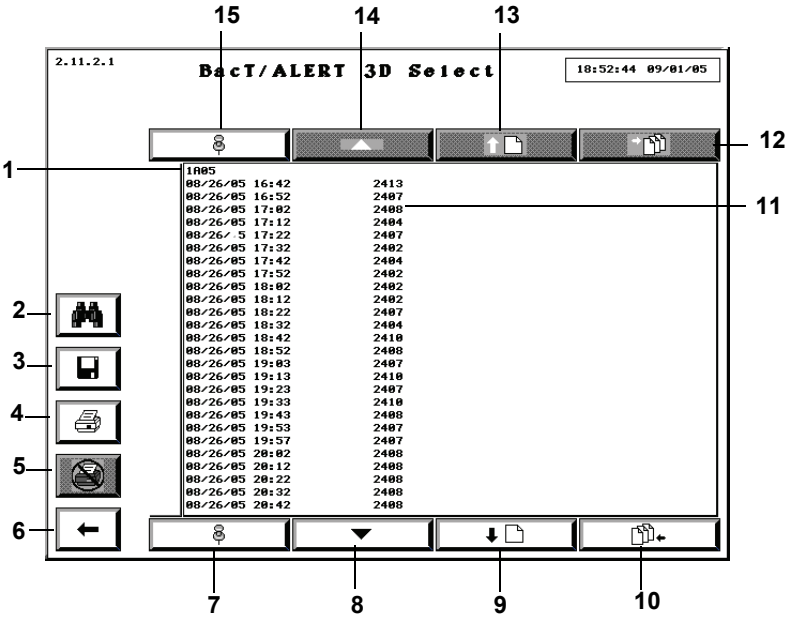


Figure 4-16: Bottle Readings Screen

1 — Bottle Cell Location
2 — Find Text Button
3 — Save Button
4 — Print Button
5 — Cancel Print Button
6 — Previous Screen Button
7 — Anchor Display Bottom Button
8 — Line Scroll Down Button
9 — Page Scroll Down Button
10 — End Scroll Button
11 — Bottle Reading (Date/ Time/Reading)
12 — Home Scroll Button
13 — Page Scroll Up Button
14 — Line Scroll Up Button
15 — Anchor Display Top Button

2) To scroll up or down a data line, click the appropriate **Line** scroll button or click the appropriate ↑ or ↓ key on the keyboard.

Note: *The **Line** scroll buttons are disabled if there are no data lines in the indicated direction.*

3) To scroll up or down a data page, click the appropriate **Page** scroll button or click the appropriate **Page Up** or **Page Down** key on the keyboard.

Note: *The **Page** scroll buttons are disabled if there are no data lines in the indicated direction.*

4) To scroll up to the oldest data line (the first data record in the report), click the **Home** scroll button or click the **Home** key on the keyboard.

Note: *The **Home** scroll button is disabled if there are no report data lines in the indicated direction.*

5) To scroll down to the newest data line (the last data record in the report), click the **End** scroll button or click the **End** key on the keyboard.

Note: *The **End** scroll button is disabled if there are no report data lines in the indicated direction.*

6) To print the bottle readings, click the **Print** button.

Note: *The **Print** buttons are only available if a printer is configured for the system. To configure a printer for the system, contact your local bioMérieux Representative.*

7) While the report is printing:

- All **Print** and **Save** buttons are disabled.
- The operator may, however, view and scroll through the displayed list, search for text in the displayed list, or exit the Bottle Readings screen and perform other operations.
- The **Cancel Print** button becomes available.

8) Click the **Cancel Print** button to stop sending data to the printer and to empty the queue of any data waiting to be sent to the printer.

Note: *Once the cancellation has been completed the **Print** and **Save** buttons will become enabled, and the **Cancel Print** button will be disabled.*

9) To specify a text string and initiate a search of the report data for the specified text, click the **Find Text** button.

The Find Text screen appears.

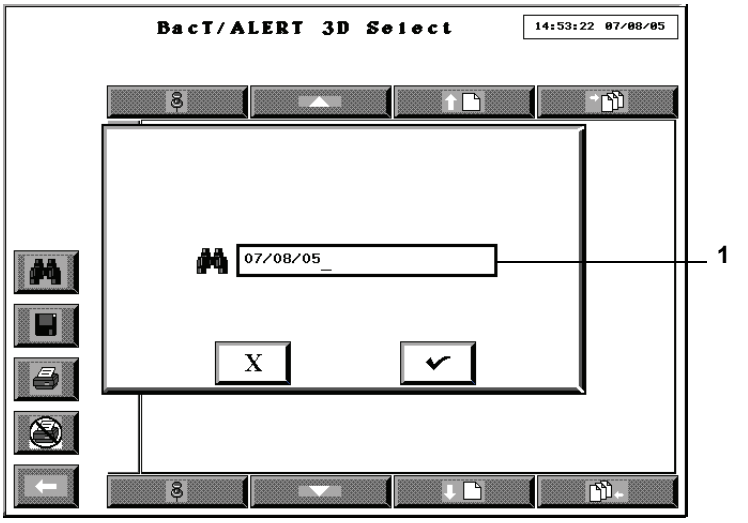


Figure 4-17: Find Text Screen

1 — Find Text Field

Use the keyboard to enter the text you wish to seek, and click the **Check** button to return to the Bottle Readings screen. Clicking the **Cancel** button will cancel the search request and return to the Bottle Readings screen.

Note: *The search will be performed upon returning to the report screen starting from the top of the report. The record that contains the first occurrence of the text will be scrolled to the first line of data displayed and the text itself will be highlighted for reference.*

If no occurrence of the specified text is found, the data displayed will not change and no reference highlighting will occur.

10) To find the next instance of the specified text, press the **F3** key on the keyboard.

Note: *If no new instance of the text is found, the data displayed, and the highlighted text will remain the same.*

11) To save the bottle readings to a text file, click the **Save** button.

The Save To File screen appears.

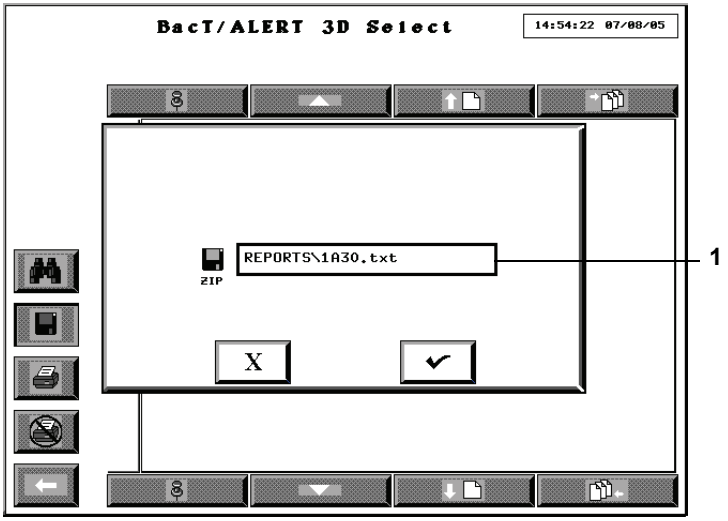


Figure 4-18: Save to File Screen

1 — File Name Field

Note: *The default file name and path will appear automatically in the **File Name** field. Use the keyboard to change the name of the file.*

Note: *All reports are saved to the pathname, **D:\REPORTS**, either using the default file name or a specified file name. All reports are automatically given an extension of **.TXT**.*

12) Place the backup media in the backup drive.

Note: *Backup media can either be a Zip® disk or a USB flash drive.*

13) Click the **Check** button to initiate the save and return to the Bottle Readings screen. Clicking the **Cancel** button will cancel the save request and return to the Bottle Readings screen.

Note: *The **Print** buttons will be disabled while the save is taking place. Once the save has completed, the **Print** buttons will be enabled.*

WARNING

Do not insert any object, other than a Zip® disk, into the Zip® drive under any circumstances.

CAUTION: Do not forcibly remove the Zip® disk from the instrument. Forcibly removing the Zip® disk may cause damage to the Zip® disk or Zip® drive and may cause the system to lock up.

14) Click the **Previous Screen** button to return to the screen from which the Bottle Readings screen was accessed.

15) When done, click the **Previous Screen** button to return to the Graph Bottle Readings screen.

Sending/Requesting LIS Information

Results can be manually sent to and demographics can be manually requested from an LIS when the BacT/ALERT® 3D SelectLink configuration is used.

Note: *The system can be configured to perform these functions automatically. To adjust these settings, call your local bioMérieux Representative.*

Note: *The arrows on the **Manual Send Test Results** and **Manual Request Test Orders** buttons also serve as an indicator of automatic data transfer.*

Sending Results to the LIS

1) From the Main screen (see Figure 4-1), click the **Manual Send Test Results** button ( ).

The arrow on the button face will blink during the transfer.

Note: *Only accessions with one or more bottles that have had a status change to positive, or that have reached maximum test time with a negative status and have been unloaded, since the last transfer will be sent.*

Requesting Information from the LIS

1) From the Main screen (see Figure 4-1), click the **Manual Request Test Orders** button ( ).

The arrow on the button face will blink during the transfer.

EDITING TEST DATA 5

About This Chapter

This chapter provides you with procedures for viewing and editing bottle data.

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Selecting Bottles Using the Select Bottle to Edit/Graph Button • 5-4

Editing Bottle Details Using the Edit Bottle Detail Screen • 5-5

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Initiating the Edit Data Relationships Function • 5-12

Editing Bottle ID to Accession Number Relationships • 5-13

Editing Accession Number to Hospital ID Relationships • 5-15

Editing Hospital ID to Patient Name Relationships • 5-17

Viewing/Editing Bottle Data

Introduction

By accessing the Edit Bottle Detail screen of both currently loaded and recently unloaded bottles, the following bottle editing functions can be performed:

- Identifying an anonymous bottle
- Editing a bottle ID
- Editing the maximum test time of a currently loaded bottle
- Editing a bottle type
- Manually changing a bottle's test result
- Unloading a bottle from a faulty rack

Note: *The bottle record must be one of the 1,920 bottle records stored in the database.*

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Access the Edit Bottle Detail screen for a specific bottle. There are two methods you can use to access the Edit Bottle Detail screen:

- Select loaded bottles using the **Edit Cell Contents** button ( ). See Selecting Bottles Using the Edit Cell Contents Button on page 5-3.

or

- Select loaded and recently unloaded bottles using the **Select Bottle to Edit/Graph** button ( ). See Selecting Bottles Using the Select Bottle to Edit/Graph Button on page 5-4.

3) Edit the bottle details as necessary (see Editing Bottle Details Using the Edit Bottle Detail Screen on page 5-5).

4) Click the **Check** button to save the changes and exit the screen or click the **Cancel** button to restore the information originally displayed and exit the screen.

Selecting Bottles Using the Edit Cell Contents Button

Note: *This function can only be used for currently loaded bottles. To view information of recently unloaded bottles, select the bottle from the Select Bottle to Edit/Graph screen (see Selecting Bottles Using the Select Bottle to Edit/Graph Button on page 5-4).*

1) From the Setup screen (see Figure 4-9), click the **Edit Cell Contents** button.

The Edit Cell Contents screen appears.

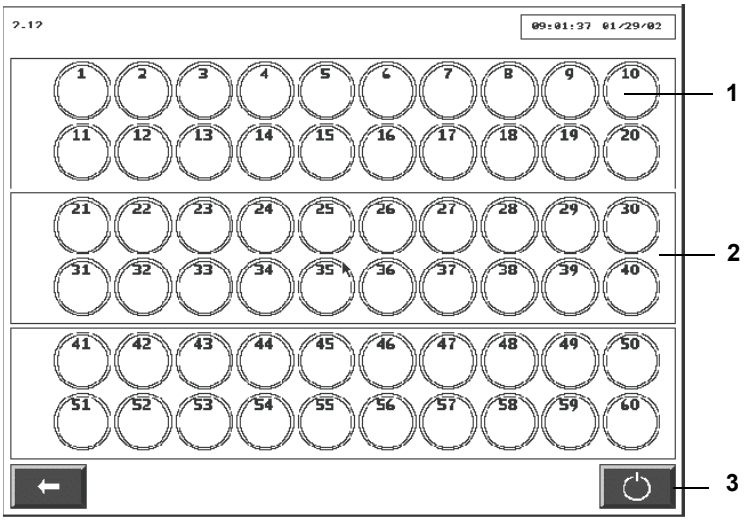


Figure 5-1: Edit Cell Contents Screen

1 — Cell

2 — Rack

3 — Restart Incubation Chamber Button

Note: *The Edit Cell Contents screen displays the same information as the View Cell Status screen (see Understanding the View Cell Status Screen Display in Chapter 4) and is continuously updated.*

2) Click the appropriate **Cell** icon.

The Edit Bottle Detail screen appears (see Editing Bottle Details Using the Edit Bottle Detail Screen on page 5-5).

Selecting Bottles Using the Select Bottle to Edit/Graph Button

1
2
3

1) From the Setup screen (see Figure 4-9), click the **Select Bottle to Edit/ Graph** button.

The Select Bottle to Edit/Graph screen overlays and disables the Setup screen.

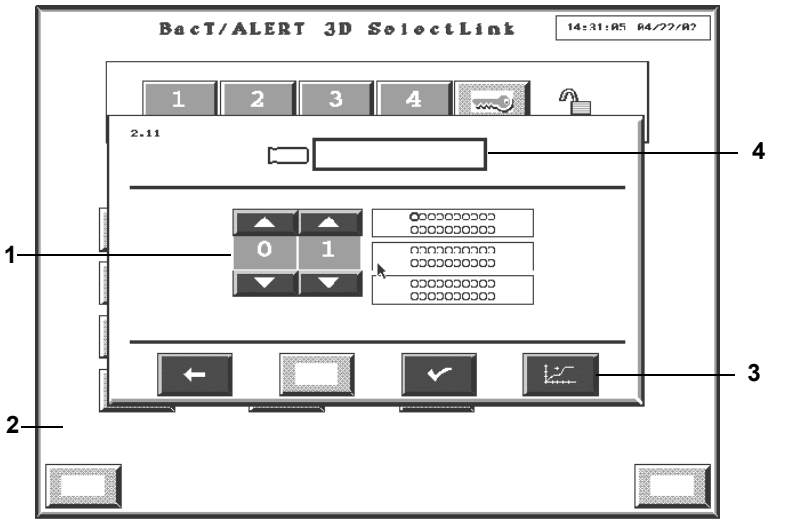


Figure 5-2: Select Bottle to Edit/Graph Screen

1 — Cell Scroll Buttons

2 — Setup Screen (Disabled)

3 — Graph Bottle Readings Button

4 — Bottle ID Field

2) If the bottle ID is known, then enter the *bottle ID* in the **Bottle ID** field (see Text/Data Entry in Chapter 4) and proceed to Step 4.

Note: *Only the last 1,920 bottles loaded can be retrieved. Any other entry in the **Bottle ID** field is invalid and will cause an Operator Error 940 (see Operator Error Codes in Chapter 8).*

3) If the cell location (but not bottle ID) is known, then adjust the **Cell** (1 – 60) scroll buttons to select the appropriate bottle location.

Note: *Only cell locations with currently loaded bottles can be used to view/edit bottle data. To view data of recently unloaded bottles, you must use the **Bottle ID** field.*

4) Click the **Check** button.

The Edit Bottle Detail screen appears (see Editing Bottle Details Using the Edit Bottle Detail Screen on page 5-5).

Editing Bottle Details Using the Edit Bottle Detail Screen

Note: *The bottle record can be edited before and after the bottle has been unloaded from the system.*

If a bottle has not already been selected, select a bottle to edit using either the **Edit Cell Contents** or the **Select Bottle to Edit/Graph** button as described in Selecting Bottles Using the Edit Cell Contents Button on page 5-3, and Selecting Bottles Using the Select Bottle to Edit/Graph Button on page 5-4.

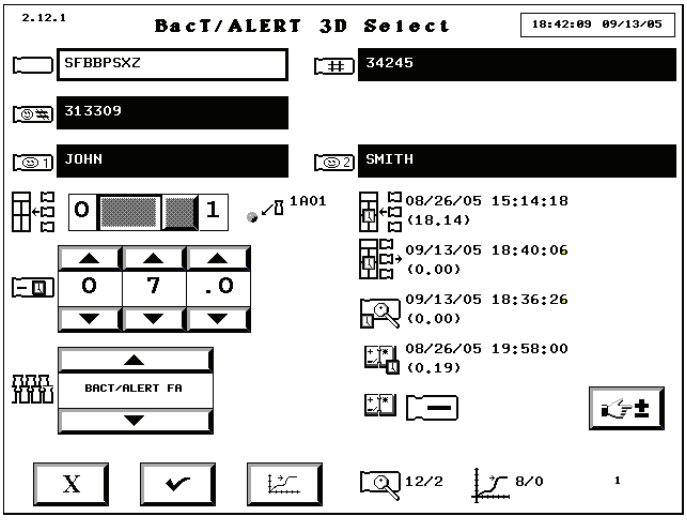
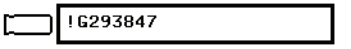


Figure 5-3: Edit Bottle Detail Screen

The screen ID is determined by the method in which the Edit Bottle Detail screen was accessed. The screen behaves in the same way regardless of how it is accessed.

- The screen ID is 2.11.1 if you access it from the Select Bottle to Edit/Graph screen.
- The screen ID is 2.12.1 if you access it from the Edit Cell Contents screen.

Edit Bottle ID Field 

A blank **Bottle ID** field indicates the bottle is currently anonymous. To assign a bottle ID to an anonymous bottle or edit the bottle ID of an identified bottle:

1) Click the **Bottle ID** field (the field turns white).

2) Manually enter the bottle ID using the keyboard or scan the barcode (see Text/Data Entry in Chapter 4).

3) Click the **Check** button.

View Accession Number Field

Disabled field that displays the accession number associated with the displayed bottle record.

View Hospital ID Field

Disabled field that displays the hospital ID associated with the displayed bottle record.

View Patient First Name Field

Disabled field that displays the patient first name associated with the displayed bottle record.

View Patient Last Name Field

Disabled field that displays the patient last name associated with the displayed bottle record.

Note: *The **View Accession Number**, **View Hospital ID**, **View Patient First Name** and **View Patient Last Name** fields are "view-only" fields.*

Note: *The fields may also be made unavailable manually. To make the field(s) unavailable, call your local bioMérieux Representative.*

Edit Load Status Slidebar Switch

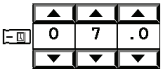
It is possible to change the load status of an identified bottle in a faulty rack from loaded to unloaded. However, it is not possible to change a bottle's load status from unloaded to loaded.

Slidebar interpretation:

- **0** = unloaded
- **1** = loaded

Note: *The slidebar is disabled if the associated rack is functioning properly.*

Edit Maximum Test Time Scroll Buttons



Displays the incubation period for the selected bottle after which the bottle's status will change from negative-to-date to negative.

Note: *The maximum test time of a bottle can be edited in days and tenths of a day at any time.*

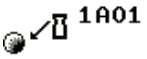
Edit Bottle Type Scroll Button

Displays the media type of the selected bottle. Use the scroll buttons to select the appropriate bottle type.

Note: *Anonymous bottles loaded into a **BC** type Incubation Chamber are assigned to the UNKNOWN bottle type.*

Note: *The **Bottle ID**, **Load Status**, **Maximum Test Time**, and **Bottle Type** fields can be edited concurrently or one at a time. Click the **Check** button to save changes.*

View Cell Location Icon

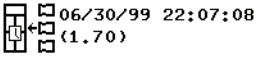


Displays the location of the selected bottle. The location is either the current location or the last cell location, depending on whether the bottle is still loaded.

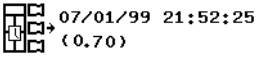
Cell ID consists of the following three components in order:

- Incubation Chamber # (Always 1)
- Drawer letter (Always A)
- Cell #

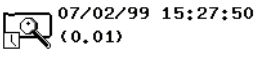
Note: *In order to maintain consistency with the BacT/ALERT® 3D family, the cell ID includes incubation module and Drawer IDs as well as cell IDs. Incubation Module and Drawer IDs cannot be changed.*

View First Loaded Time Icon 

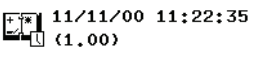
Displays the date and time the selected bottle was first loaded into the system. The number of days since the bottle was first loaded appears in parenthesis below the date and time.

View Last Unloaded Time Icon 

Displays the date and time the selected bottle was last unloaded from the system. The number of days since the bottle was unloaded appears in parenthesis below the date and time. No time will be displayed if the bottle has never been unloaded.

View Time of Last Bottle Reading Icon 

Displays the date and time of the last bottle reading that was successfully processed by the detection algorithm. The number of days since the last bottle reading was processed appears in parenthesis below the date and time of the last bottle reading.

View Test Time Icon 

Displays the date and time the last test result changed. The number of days that have passed between load and last determination appears in parenthesis below the date and time. The date and time will not be displayed if the bottle's status has not change from negative-to-date.

View Test Result Icon

Displays the test status of the selected bottle. Test status is displayed inside the bottle icon:

+	Positive (yellow bottle)
-	Negative (green bottle)
*	Negative-to-date (gray bottle)
~ +	Critical determination in progress (gray bottle)

Edit Test Result Button

You can use the **Edit Test Result** button to change the status of the displayed bottle:

1) Click the **Edit Test Result** button.

The Edit Test Result screen overlays and disables the Edit Bottle Detail screen.

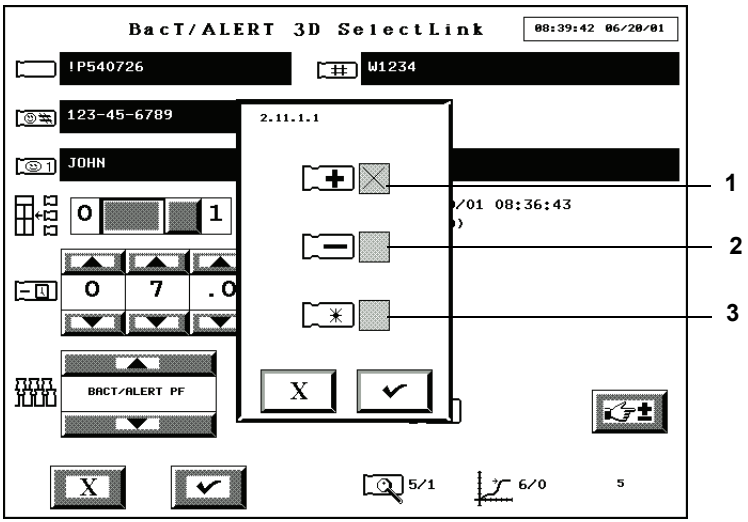


Figure 5-4: Edit Test Result Screen

1 — Positive Status Checkbox
2 — Negative Status Checkbox
3 — Negative-To-Date Status Checkbox

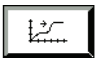
2) Click the checkbox that corresponds to the desired status to insert an **X**.

3) Click the **Check** button to accept the change and return to the Edit Bottle Detail screen, or click the **Cancel** button to keep the current status and return to the Edit Bottle Detail screen.

Note: *Results that have been manually changed via the Edit Bottle Detail screen (see Editing Bottle Details Using the Edit Bottle Detail Screen on page 5-5) will be marked on the report with a stick figure (🚹).*

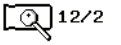
Note: *If a bottle is positive (set manually, or positive by any other reason) and then is manually changed to negative-to-date, the stick figure (🚹) will not appear.*

Graph Bottle Readings Button



Displays the bottle graph on the Graph Bottle Readings screen (see Viewing and Printing Bottle Graphs in Chapter 4).

View Algorithm/Polynomial Icon



The number above the slash represents the type of bottle specific algorithm used for the data analysis of the selected bottle.

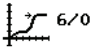
Table 5-1: Bottle Specific Algorithms

Algorithm No.	Bottle Type
11	SA Plastic, SN Plastic
12	FA Plastic
13	MP Plastic
15	PF Plastic
17	MB Glass

The number below the slash represents the type of polynomial. There are two types of polynomials:

- Polynomial 1 — LES Glass
- Polynomial 2 — LES Plastic

View How Determined/Positivity Index Icon



The number above the slash displays a numerical code representing how the selected bottle's status was determined.

Table 5-2: Status Determination Codes

Status Determination Code	How Status Determined
1	Rate
2	Acceleration
3	Initial value
4	Maximum test time exceeded

Table 5-2: Status Determination Codes (Continued)

Status Determination Code	How Status Determined
5	Delta
6	Test in progress
7	Manual (changed at Database Management System)
8	Manual (changed at BacT/ALERT® 3D 60)
9	Algorithm change (see Fault Code 74)
10	Manual (changed by LIS)
20 – 23	Corrupted bottle record
200 – 204	Detection of invalid data
205	Missing Readings

The number below the slash is the Positivity Index. An index less than 1 indicates a negative or negative-to-date bottle. An index greater than or equal to 1 indicates a positive bottle.

Note: *The number displayed on the lower right of the Edit Bottle Detail screen (not associated with an icon) is a bottle sequence number, which may be utilized by your bioMérieux Representative.*

Editing Data Relationships

Introduction

Bottle information (Bottle ID, Accession Number, Hospital ID, Patient First Name, Patient Last Name) is typically associated to a bottle when a bottle is loaded. If necessary, however, these values can later be changed by editing the data relationships. This is initiated by clicking the **Edit Data Relationships** button on the Setup screen.

The following sections will cover:

- Initiating the Edit Data Relationships function (see Initiating the Edit Data Relationships Function on page 5-12).
- Editing Bottle ID to Accession Number relationships (see Editing Bottle ID to Accession Number Relationships on page 5-13).

- Editing Accession Number to Hospital ID relationships (see Editing Accession Number to Hospital ID Relationships on page 5-15).
- Editing Hospital ID to Patient Name relationships (see Editing Hospital ID to Patient Name Relationships on page 5-17).

Initiating the Edit Data Relationships Function

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the **Edit Data Relationships** button ( ).

The Edit Data Relationships screen appears.

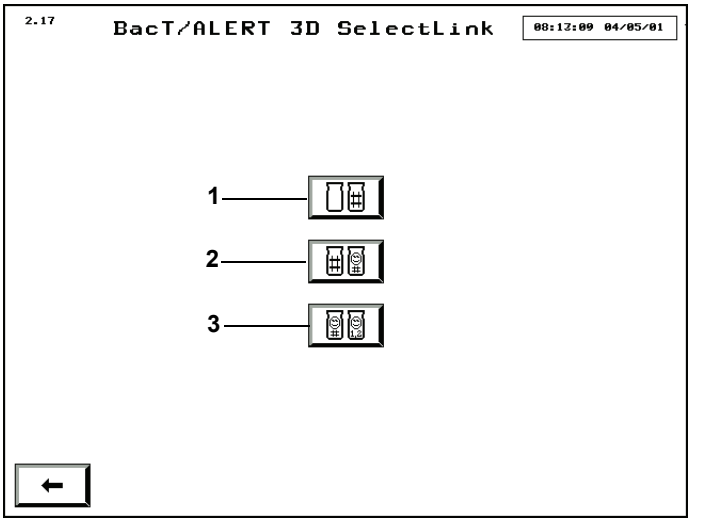


Figure 5-5: Edit Data Relationships Screen

1 — Edit Bottle ID to Accession Number Relationships Button
2 — Edit Accession Number to Hospital ID Relationships Button
3 — Edit Hospital ID to Patient Name Relationships Button

Note: *The availability of the buttons also depends on the availability of the fields. Example: If the **Patient First Name** and **Patient Last Name** fields are unavailable on the system, then the **Edit Hospital ID to Name Relationships** button is not available*

3) To edit a Bottle ID to accession number relationship, click the corresponding button and see Editing Bottle ID to Accession Number Relationships on page 5-13.

4) To edit an Accession Number to Hospital ID relationship, click the corresponding button and see Editing Accession Number to Hospital ID Relationships on page 5-15.

5) To edit a Hospital ID to patient name relationship, click the corresponding button and see Editing Hospital ID to Patient Name Relationships on page 5-17.

Editing Bottle ID to Accession Number Relationships

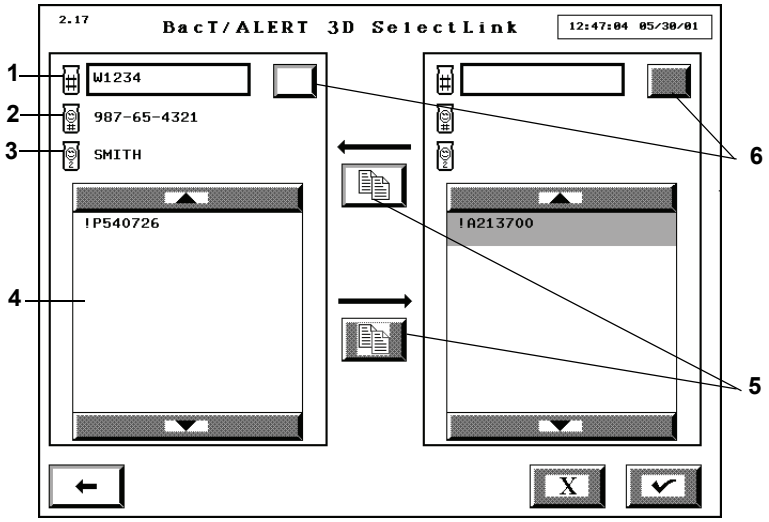


Figure 5-6: Edit Bottle ID to Accession Number Relationships Screen

1 — Accession Number Field
2 — Hospital ID Field
3 — Patient Last Name Field
4 — Bottle ID Scroll Box
5 — Data Transfer Buttons
6 — Accession Number Selection Buttons

Note: *The **Accession Number Selection** button will only appear if the system is set to allow reuse of accession numbers. By default, the BacT/ALERT® 3D 60 is set to regard accession numbers as always unique. If you desire to re-use accession numbers, contact your local bioMérieux Representative.*

Note: *When the Edit Bottle ID to Accession Number Relationships screen is first accessed, the **Accession Number** field is blank and all bottle IDs not associated with an Accession Number are displayed in both **Bottle ID** scroll boxes.*

Attaching Bottle IDs Without an Accession Number to an Accession Number

1) Access the Edit Bottle ID to Accession Number Relationships screen (see Initiating the Edit Data Relationships Function on page 5-12).

2) Enter the *accession number* in the left **Accession Number** field that you wish to associate to the bottle(s).

   If the entered accession number is associated with more than one hospital ID, use the **Accession Number Selection** button to scroll through each instance as indicated in the **Hospital ID** and **Patient Last Name** fields.

3) Click the bottle ID(s) in the right **Bottle ID** scroll box to be associated with the accession number. The selected bottle ID(s) highlight.

4) Click the top **Data Transfer** button to move the Bottle ID(s) to the left **Bottle ID** scroll box.

5) Click the **Check** button to accept the changes, or click the **Cancel** button to restore all relationships originally displayed.

6) When done, click the **Previous Screen** button to return to the Edit Data Relationships screen.

Note: *If the Edit Bottle ID to Accession Number Relationships screen was accessed directly from the Setup screen, then the **Previous Screen** button will return to the Setup screen.*

Moving a Bottle ID Association from one Accession Number to Another

1) Access the Edit Bottle ID to Accession Number Relationships screen (see Initiating the Edit Data Relationships Function on page 5-12).

2) Enter the *accession number* in the left **Accession Number** field to which the bottle(s) is currently associated.

   If the entered accession number is associated with more than one hospital ID, the **Accession Number Selection** button can be used to scroll through each instance as indicated in the **Hospital ID** and **Patient Last Name** fields.

3) Enter the *accession number* in the right **Accession Number** field that you wish to associate to the bottle(s).

   If the entered accession number is associated with more than one hospital ID, the **Accession Number Selection** button can be used to scroll through each instance as indicated in the **Hospital ID** and **Patient Last Name** fields.

4) Click the bottle ID(s) in the left **Bottle ID** scroll box that are to be transferred. The selected bottle ID(s) highlight.

5) Click the bottom **Data Transfer** button to move the bottle ID(s) to the right **Bottle ID** scroll box.

6) Click the **Check** button to accept the changes, or click the **Cancel** button to restore all relationships originally displayed.

7) When done, click the **Previous Screen** button to return to the Edit Data Relationships screen.

Note: *If the Edit Bottle ID to Accession Number Relationships screen was accessed directly from the Setup screen, then the **Previous Screen** button will return to the Setup screen.*

Editing Accession Number to Hospital ID Relationships

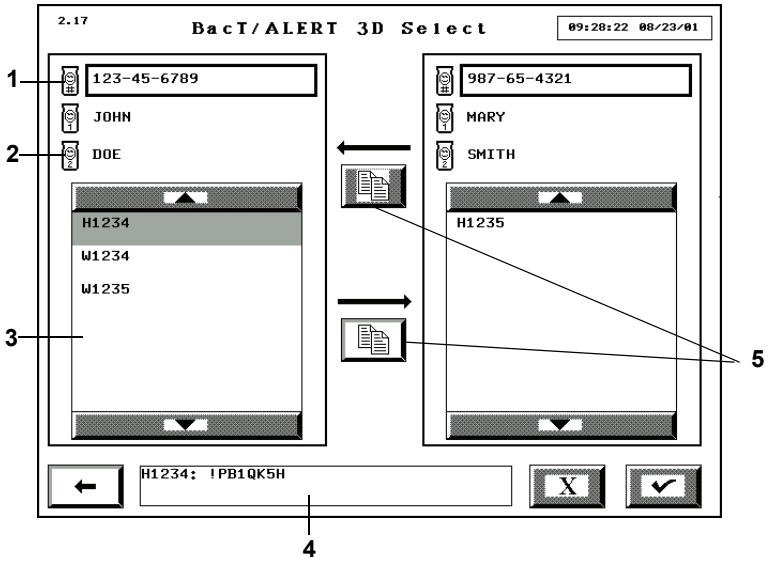


Figure 5-7: Edit Accession Number to Hospital ID Relationships Screen

1 — Hospital ID Field
2 — Patient Last Name Field
3 — Accession Number Scroll Box
4 — Bottle ID List Box
5 — Data Transfer Buttons

Note: *When the Edit Accession Number to Hospital ID Relationships screen is first accessed, the **Hospital ID** field is blank and all accession number(s) not associated with a hospital ID are displayed in both **Accession Number** scroll boxes.*

Attaching Accession Numbers Without a Hospital ID to a Hospital ID

1) Access the Edit Accession Number to Hospital ID Relationships screen (see Initiating the Edit Data Relationships Function on page 5-12).
2) Enter the *hospital ID* in the left **Hospital ID** field that you wish to associate to the accession number(s).
3) Click the accession number(s) in the right **Accession Number** scroll box that are to be associated to the hospital ID.

   The selected accession number(s) highlight. The bottle IDs associated with the accession number that was clicked last is displayed in the **Bottle ID** list box.
4) Click the top **Data Transfer** button to move the accession number(s) to the left **Accession Number** scroll box.
5) Click the **Check** button to accept the changes, or click the **Cancel** button to restore all original relationships.
6) When done, click the **Previous Screen** button to return to the Edit Data Relationships screen.

Note: *If the Edit Accession Number to Hospital ID Relationships screen was accessed directly from the Setup screen, then the **Previous Screen** button will return to the Setup screen.*

Moving an Accession Number Association from one Hospital ID to Another

1) Access the Edit Accession Number to Hospital ID Relationships screen (see Initiating the Edit Data Relationships Function on page 5-12).
2) Enter the *hospital ID* in the left **Hospital ID** field that the accession number(s) is currently associated.
3) Enter the *hospital ID* in the right **Hospital ID** field with which you wish to associate to the accession number(s).
4) Click the accession number(s) in the left **Accession Number** scroll box that are to be transferred.

   The selected accession number(s) highlight. The bottle IDs associated with the accession number that was clicked last is displayed in the **Bottle ID** list box.
5) Click the bottom **Data Transfer** button to move the accession number(s) to the right **Accession Number** scroll box.
6) Click the **Check** button to accept the changes, or click the **Cancel** button to restore all relationships originally displayed.

7) When done, click the **Previous Screen** button to return to the Edit Data Relationships screen.

Note: *If the Edit Accession Number to Hospital ID Relationships screen was accessed directly from the Setup screen, then the **Previous Screen** button will return to the Setup screen.*

Editing Hospital ID to Patient Name Relationships

1) Access the Edit Hospital ID to Patient Name Relationships screen (see Initiating the Edit Data Relationships Function on page 5-12).

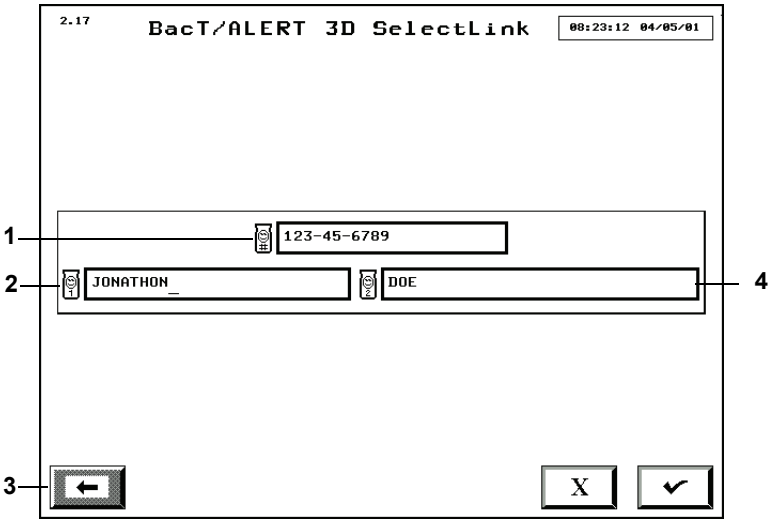


Figure 5-8: Edit Hospital ID to Patient Name Relationships Screen

1 — Hospital ID Field
2 — Patient First Name Field
3 — Previous Screen Button
4 — Patient Last Name Field

2) Enter the *hospital ID* in the **Hospital ID** field for which you want to add/edit the patient name association.

3) Enter the correct *patient name* into the **Patient First Name** and **Patient Last Name** fields.

4) Click the **Check** button to accept the changes, or click the **Cancel** button to restore all relationships originally displayed.

5) When done, click the **Previous Screen** button to return to the Edit Data Relationships screen.

Note: *The **Patient First Name** and **Patient Last Name** fields will remain unavailable until a known hospital ID is entered.*

Note: *If the Edit Hospital ID to Patient Name Relationships screen was accessed directly from the Setup screen, then the **Previous Screen** button will return to the Setup screen.*

SOFTWARE CONFIGURATION 6

About This Chapter

This chapter provides you with procedures on how to configure the software.

Chapter Contents

Setting the Maximum Test Time • 6-2
Setting the Audible Alarms • 6-3
Priority of Alarms • 6-5
Terminating an Instrument Alarm • 6-5
Changing the System Password • 6-5
Initiating Manual Backup • 6-7
Configuring Report Screens • 6-9
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Entering Report Labels • 6-9
Configuring Report Contents • 6-13
Viewing and Printing Calibration Data • 6-19
Viewing and Printing Calibration History • 6-22

Setting the Maximum Test Time

Perform the following procedure to set a universal maximum test time (or time that a negative-to-date bottle will be tested before being called final negative) for each media type. The result is that each time a bottle is loaded, its maximum test time will default to the maximum test time configured for its media type.

Note: *The maximum test time can be changed for an individual bottle while loading if desired, or can be changed after a bottle is loaded in the Edit Bottle Detail Screen. See Changing the Maximum Test Time (Individual Bottles) in Chapter 4.*

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the **Set Maximum Test Time** button ( ).

The Set Maximum Test Time screen overlays and disables the Setup screen.

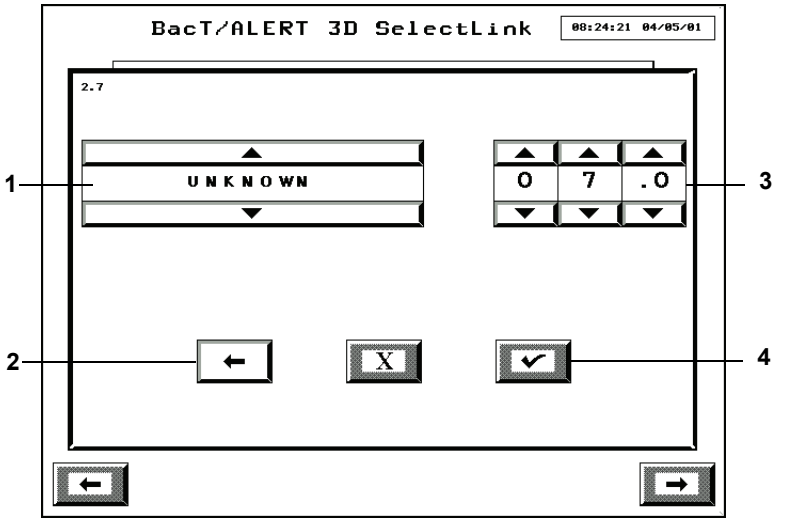


Figure 6-1: Set Maximum Test Time Screen

1 — Media Type Scroll Button

2 — Previous Screen Button

3 — Incubation Period Scroll Buttons

4 — Check Button

3) Select the appropriate bottle type from the **Media Type** scroll button.

4) Set the incubation period in days and tenths of a day using the **Incubation Period** scroll buttons.

Note: *The minimum test time that can be specified is 0.1 day.*

5) Click the **Check** button to save the maximum test time settings, or click the **Cancel** button to return the system to the previous maximum test time settings.

Note: *Changing the maximum test time has no affect on bottles currently loaded. The new maximum test time will be attributed to bottles loaded after the setting is changed.*

6) Click the **Previous Screen** button to return to the Setup screen.

Setting the Audible Alarms

You can enable/disable the following audible alarms:

- **Positive Bottle Alarm** – A repeated sequence of brief beeps followed by a pause. This sequence of beeps are repeated every 60 seconds until the bottle is removed.
- **Instrument Fault Alarm** – An ongoing, continuous sequence of brief beeps. Once the condition is acknowledged (see Terminating an Instrument Alarm on page 6-5), the alarm will sound again in 30 minutes if the error condition still exists.

Note: *The default setting for the fault reminder period is 30 minutes. If you require a different time period, contact your local bioMérieux Representative.*

- **Operator Error Alarm** – Two brief beeps to alert the operator to look at the Monitor where an error code or picture is displayed. For resolution of a specific error code, see Operator Error Codes in Chapter 8.

Note: *Operator error alarms do not repeat.*

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the **Set Audible Alarm Options** button ( ).

The Set Audible Alarm Options screen overlays and disables the Setup screen.

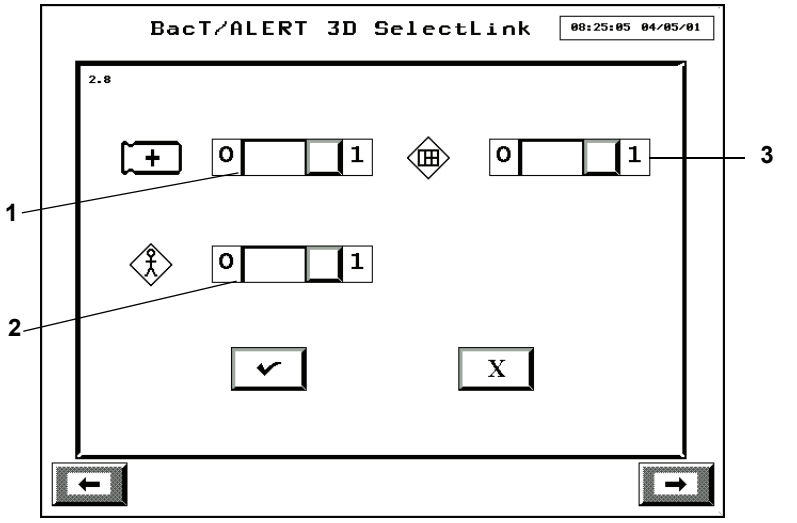


Figure 6-2: Set Audible Alarm Options Screen

1 — Positive Bottle Alarm Slidebar Switch

2 — Operator Error Alarm Slidebar Switch

3 — Instrument Fault Alarm Slidebar Switch

3) Enable and/or disable alarms by adjusting the slidebar switches to the desired settings:

- **0** — disabled
- **1** — enabled

4) Click the **Check** button to save any changes, or click the **Cancel** button to return the system to the original settings.

The system returns to the Setup screen.

Note: *In addition to the Instrument Audible Alarms, the bar code reader is also programmed to provide an audible alarm in three instances. These are:*

- *Bar code is scanned with entry to Bottle ID field*
- *Accession bar code is scanned with entry to Accession Number field*
- *Any Operator errors related to scanning, loading or unloading*

The bar code reader alarms are not disabled by setting the Operator Error Alarm slide bar to the zero setting.

Priority of Alarms

The audible alarms which will sound correspond to the most critical condition according to the priorities listed (highest to lowest) below:

1) Instrument fault

2) Positive bottles

3) Operator errors

Terminating an Instrument Alarm

To terminate an alarm, perform one of the following:

- Acknowledge the condition causing the alarm by clicking on any area of any screen of the monitor or by pressing any key on the keyboard.
- Disable the alarm.

Note: *To remove or adjust your error alarm delay cycle, contact your local bioMérieux Representative.*

Changing the System Password

Perform the following procedure to change the system password that is used to enable the Setup screen function buttons.

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the **Change Password** button ( ).

The Change Password screen overlays and disables the Setup screen.

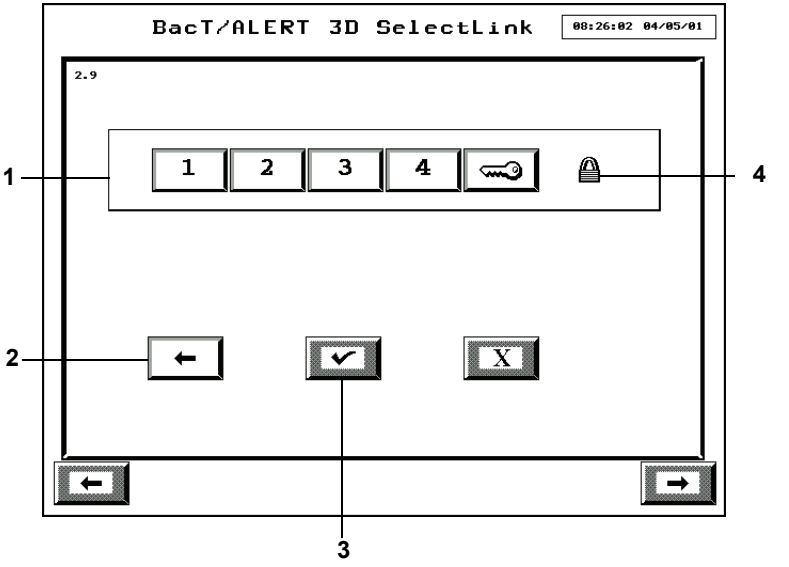


Figure 6-3: Change Password Screen

1 — Password Entry Keypad
2 — Previous Screen Button
3 — Check Button
4 — Padlock Icon

3) Enter a valid *password* using the **Password Entry Keypad** buttons.

Note: *Acceptable passwords consist of any combination of the numbers 1 to 4 and have a maximum length of eight characters.*

4) The **Padlock** icon changes to a full open position after the **Key Symbol** button is clicked. If the **Padlock** icon does not open, then repeat Step 3.

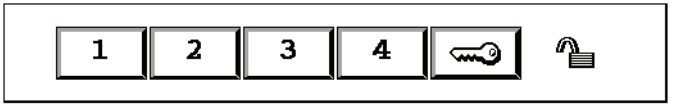


Figure 6-4: Padlock Icon (Full Open Position)

5) Enter the new *password* using the **Password Entry Keypad** buttons.

6) Click the **Key Symbol** button.

The **Padlock** icon changes to a half open position.

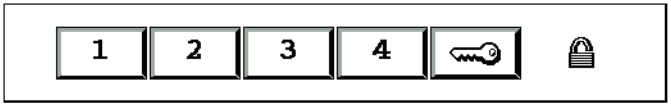


Figure 6-5: Padlock Icon (Half Open Position)

7) Re-enter the new *password* to verify.

8) Click the **Key Symbol** button. If the same password is entered both times, then the **Padlock** icon closes. If the new password was not verified correctly, the **Padlock** icon will open completely. The user must then start over with Step 5 to change the password.

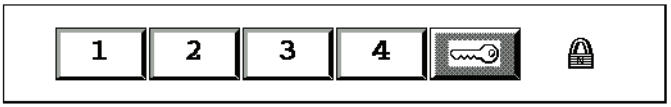


Figure 6-6: Padlock Icon (Closed Position)

9) Click the **Check** button to accept the new password, or click the **Cancel** button to retain the old password.

10) Click the **Previous Screen** button to return to the Setup screen.

Note: *Record the new password in a secure location. This password will be needed to access all function buttons on the Setup screen.*

Initiating Manual Backup

Perform the following procedure to initiate an immediate backup of the system to a Zip® disk or USB flash drive. The backup procedure, though lengthy, does not prohibit you from simultaneously performing any other functions on the system.

IMPORTANT: ***If you have a USB Port, use only USB Flash Drives provided by bioMérieux for backups.***

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the Backup Management button ( ).

The Backup Management screen overlays and disables the Setup screen.

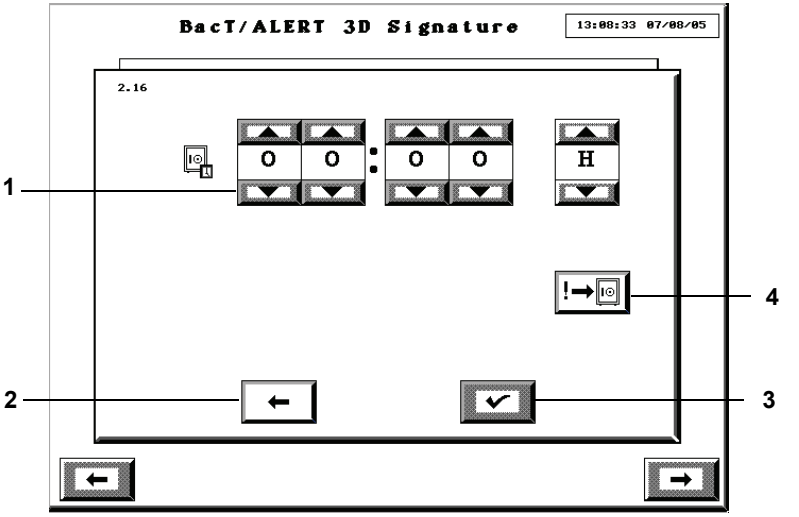


Figure 6-7: Backup Management Screen

1 — Automatic Backup Time Scroll Buttons

2 — Previous Screen Button

3 — Check Button

4 — Manual Backup Button

Note: *The **Automatic Backup Time** scroll buttons are disabled by default. If you wish to set an automatic backup time, contact your local bioMérieux Representative.*

3) To initiate an immediate backup, click the **Manual Backup** button.

The system returns to the Setup screen.

Note: *If a manual backup is initiated without a Zip® disk inserted in the drive or a USB flash drive inserted in the USB port, then an Instrument Status Code 810 will display (see Instrument Status Codes in Chapter 8).*

Note: *While the system is being backed up, the **Backup In Progress** icon will appear in the upper left corner of the Backup Management and Main screens. The icon will disappear every 5 seconds for half a second.*

Figure 6-8: Backup in Progress Icon

Note: *If you attempt to perform a function (for example, load or unload a bottle) while a manual backup is taking place, you may encounter a brief screen grayout. This is a safety feature that prevents database corruption by allowing the software to close and exit files prior to giving you access.*

Note: *If you have a 250 MB Zip® Drive, only use 250 MB Zip® disks for backups.*

Note: *If you have a 750 MB Zip® Drive, you may use either a 250 MB or 750 MB Zip® disk for backups.*

WARNING

Do not insert any object, other than a Zip® disk, into the Zip® drive under any circumstances.

CAUTION: Do not forcibly remove the Zip® disk from the instrument. Forcibly removing the Zip® disk may cause damage to the Zip® disk or Zip® drive and may cause the system to lock up.

Configuring Report Screens

Introduction

Report screens are accessed by clicking the appropriate **Display Report Screen** button from the Report Selection screen (see Viewing/Printing Reports in Chapter 4 and Figure 4-10, Report Selection Screen). Perform the following procedures to configure these report screens.

Entering Report Labels

The following procedure describes how to select labels to be used as column headings for all reportable fields on system reports.

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) From the Setup screen, click the **Report** button ( ).

The Report Selection screen appears.

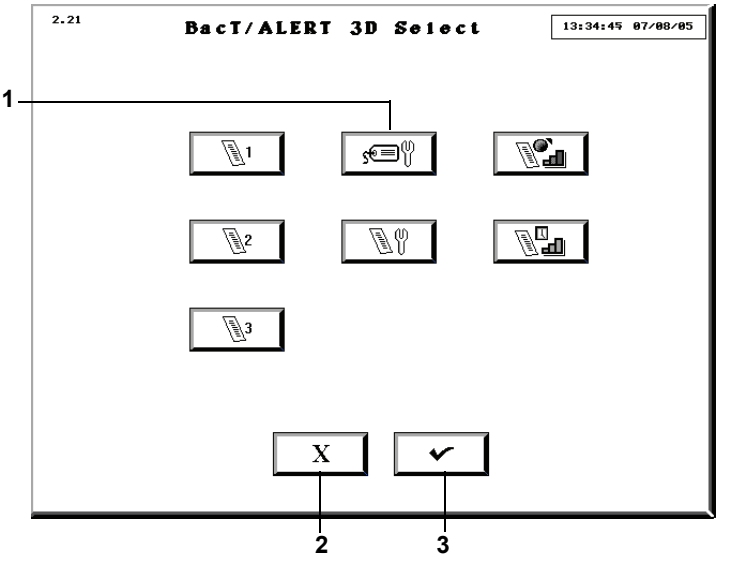


Figure 6-9: Report Selection Screen

1 — Report Label Entry Button

2 — Cancel Button

3 — Check Button

3) Click the **Report Label Entry button** ( ).

The Report Label Entry screen appears.

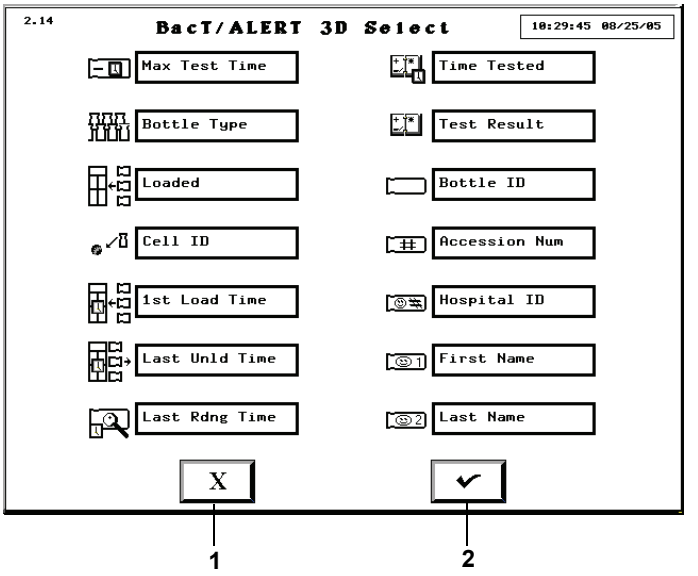


Figure 6-10: Report Label Entry Screen

1 — Cancel Button

2 — Check Button

Note: *The above default report labels are assigned at installation and can be modified or changed.*

4) Click the field where you will enter the new label.

The field turns white.

5) Enter the new *label*. Labels may contain up to 15 characters; however, labels will be truncated on the reports if the column widths do not allow room for the entire label (see Configuring Report Contents on page 6-13).

6) After all desired label changes have been made, verify that all labels are unique and that no label fields are empty.

7) Click the **Check** button to accept the label changes, or click the **Cancel** button to retain the previous labels.

The system returns to the Setup screen.

Note: *Operator Error 960 displays if the **Check** button is clicked with duplicate Report Label entries present (see Operator Error Codes in Chapter 8).*

Note: *Operator Error 961 displays if the* ***Check*** *button is clicked with blank* ***Report Label*** *fields present.*

CAUTION: The user is solely responsible for the choice of customized report label text and for validating that the intended label text appears in all associates reports. bioMérieux shall not be liable for any consequences resulting from misinterpretation of customized report labels.

Table 6-1: Report Field Descriptions

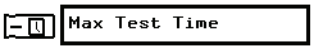
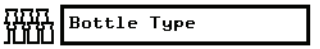
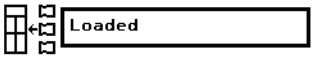
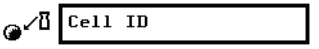
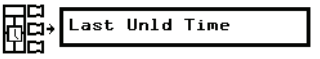
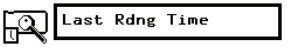
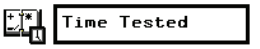
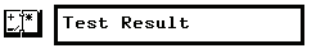
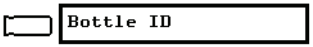
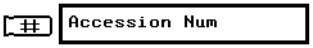
Field	Description
	Displays the maximum number of days a bottle will be tested to the tenth of a day (ex. XX.X).
	Displays the bottle type with no abbreviation.
	Displays **1** for bottle loaded or **0** for bottle not loaded.
	Displays cell location. Example: 1A01.
	Displays the date the bottle was loaded in one of the following formats, depending on Set Date/Time screen setting: MM/DD/YY or DD/MM/YY.
	Displays the date the bottle was unloaded in one of the following formats, depending on Set Date/Time screen setting: MM/DD/YY or DD/MM/YY.
	Displays the Date and Time of the last successful bottle reading in one of the following formats, depending on Set Date/ Time screen setting: MM/DD/YY HH:MM or DD/MM/YY HH:MM. The time is always displayed in 24 hour format regardless of the Set Date/Time screen setting.
	Displays the time in days since the bottle has been loaded for negative-to-date bottles, or the time it took to make the result determination for positive and negative bottles. The time is displayed in hundredths of days (ex. XX.XX).
	Displays the bottle test result as + for positive, - for negative, or * for negative to date.

Table 6-1: Report Field Descriptions (Continued)

Field	Description
	Displays the bottle ID.
	Displays the accession number or other kind of data entered by the user.
	Displays the hospital ID or other kind of data entered by the user.
	Displays the patient's first name or other kind of data entered by the user.
	Displays the patient's last name or other kind of data entered by the user.

Configuring Report Contents

Perform the following procedure to configure the Report screens to show the desired information (see Figure 4-11, Sample Report Screen).

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) From the Setup screen, click the **Report** button ( ).

The Report Selection screen appears.

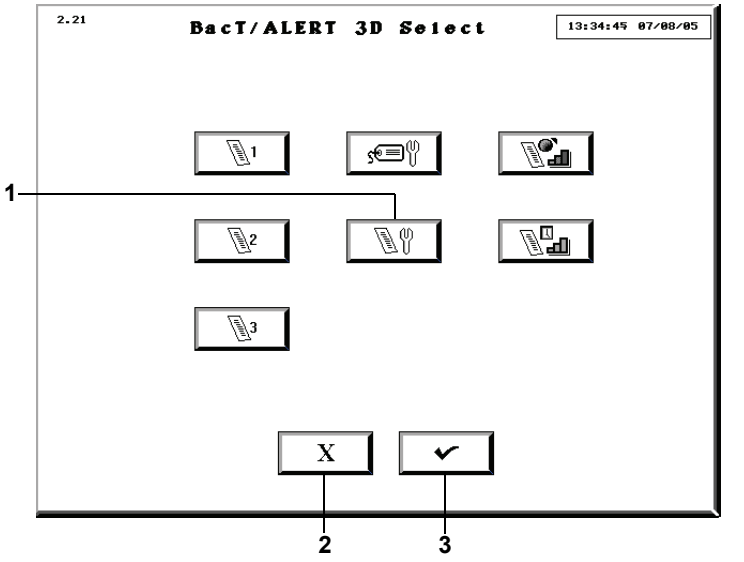


Figure 6-11: Report Selection Screen

1 — Report Configuration Button

2 — Cancel Button

3 — Check Button

3) Click the **Report Configuration** button ( ).

The Report Configuration screen appears.

See Figure 6-12, Figure 6-13, and Figure 6-14 for examples of the Load, Status, and Unload Report Configuration screens, respectively.

4) Click the **Edit Report** button that corresponds to the report you wish to reconfigure.

5) Adjust the **Column Selection** scroll buttons so that the desired fields are reported in the desired order. The scroll buttons correspond to the report columns from left to right.

Note: *Each **Column Selection** scroll button contains all reportable fields plus a blank selection so that the column can be left blank.*

6) Adjust the column widths by clicking the **Column Width** selection box under the column to be altered, and enter the new width. Make certain the column widths do not exceed the total available.

Note: *The **70** to the left of the selection boxes denotes the total available width and the number to the right of the equals sign denotes the available width left (ex. the total minus the sum of the **Column Width** selection boxes).*

7) Adjust the **Primary/Secondary Sort** scroll buttons, if desired, to sort the report.

Note: *Each **Primary/Secondary Sort** scroll button both contain all reportable fields plus a blank selection if a sort is not to be performed.*

8) Select the order of any sorts with the **Sort Order Selection** button. If the arrow is pointed upward, there will be an ascending sort and if the arrow is pointed downward, there will be a descending sort.

9) Click the **Section Break** checkbox(es) to set a section break.

Note: *A sort can be selected for a field that is not chosen as one of the report columns. If a section break is also chosen for that sort, then the fields data will display in the section break line. This, in effect, allows the user to report two extra data fields.*

10) Click the **Preview Report** button to view the report configuration (see Figure 4-11, Sample Report Screen in Chapter 4).

11) Click the **Previous Screen** button to return to the Report Configuration screen.

12) Make any adjustments to the report configuration desired.

13) Click the **Check** button to accept the changes to the report configuration, or click the **Cancel** button to retain the original configuration.

14) Click the **Previous Screen** button to return to the Setup screen.

Load Report Configuration Screen

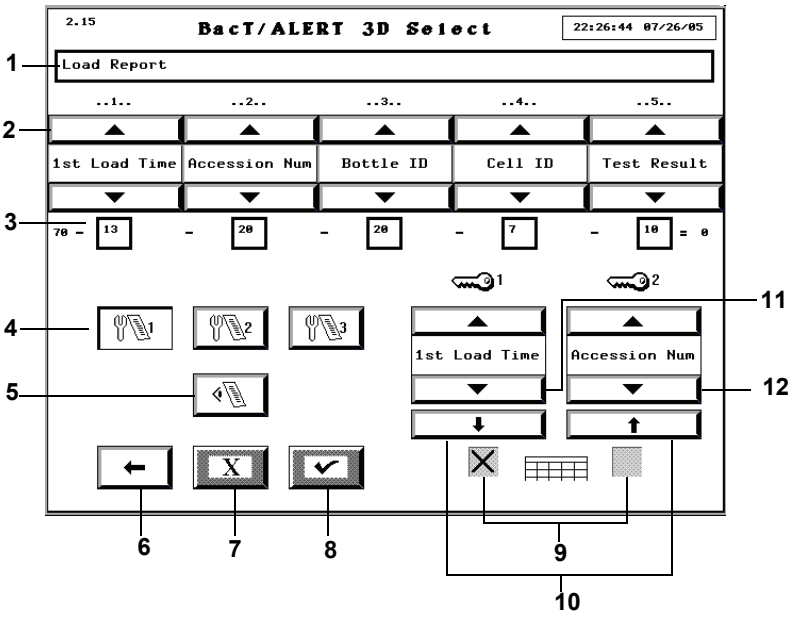


Figure 6-12: Load Report Configuration Screen

1 — Report Title
2 — Column Selection Scroll Buttons
3 — Column Width Selection Boxes
4 — Edit Report Buttons
5 — Preview Report Button
6 — Previous Screen Button
7 — Cancel Button
8 — Check Button
9 — Section Break Checkboxes
10 —Sort Order Buttons
11 — Primary Sort Scroll Button
12 — Secondary Sort Scroll Button

Status Report Configuration Screen

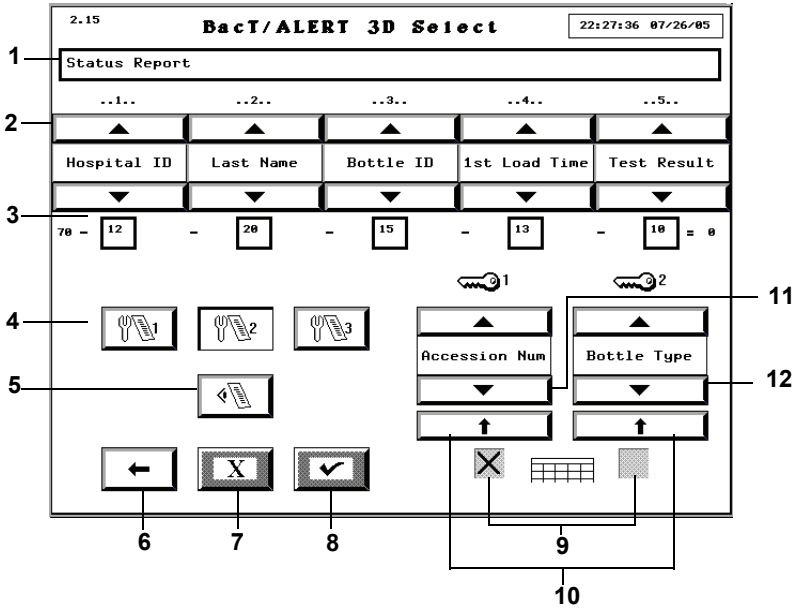


Figure 6-13: Status Report Configuration Screen

1 — Report Title
2 — Column Selection Scroll Buttons
3 — Column Width Selection Boxes
4 — Edit Report Buttons
5 — Preview Report Button
6 — Previous Screen Button
7 — Cancel Button
8 — Check Button
9 — Section Break Checkboxes
10 — Sort Order Buttons
11 — Primary Sort Scroll Button
12 — Secondary Sort Scroll Button

Unload Report Configuration Screen

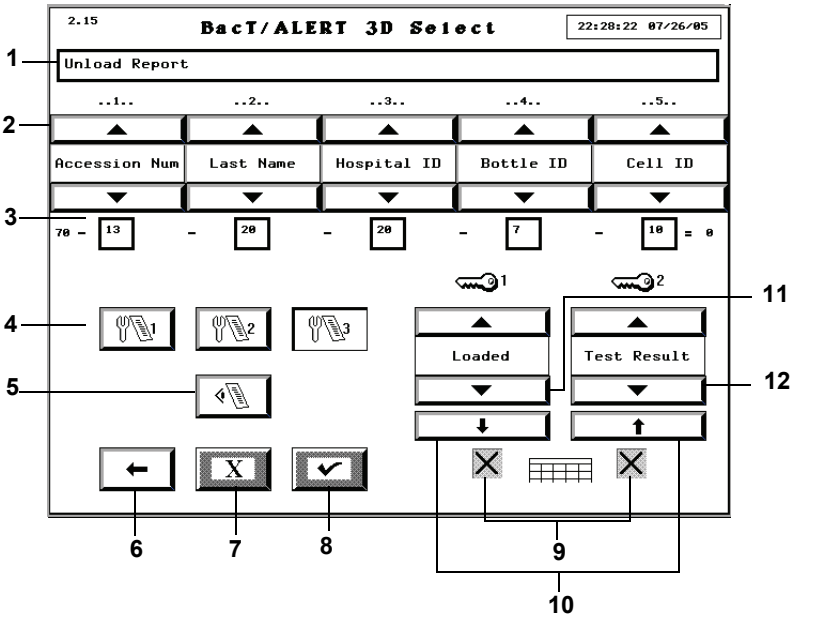


Figure 6-14: Unload Report Configuration Screen

1 — Report Title
2 — Column Selection Scroll Buttons
3 — Column Width Selection Boxes
4 — Edit Report Buttons
5 — Preview Report Button
6 — Previous Screen Button
7 — Cancel Button
8 — Check Button
9 — Section Break Checkboxes
10 — Sort Order Buttons
11 — Primary Sort Scroll Button
12 — Secondary Sort Scroll Button

Viewing and Printing Calibration Data

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) From the Setup screen, click the **Report** button ( ).

The Report Selection screen appears.

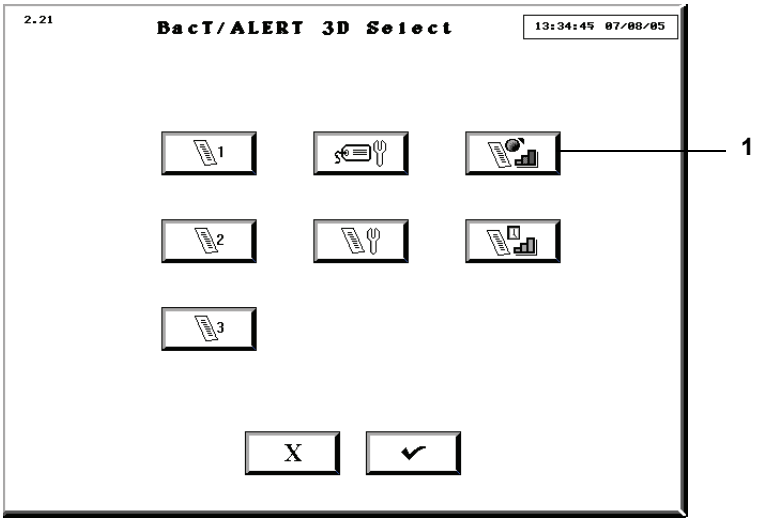


Figure 6-15: Report Selection Screen

1 — Calibration Report Button

3) Click the **Calibration Report** button ( ).

The Cell Calibration Report screen appears.

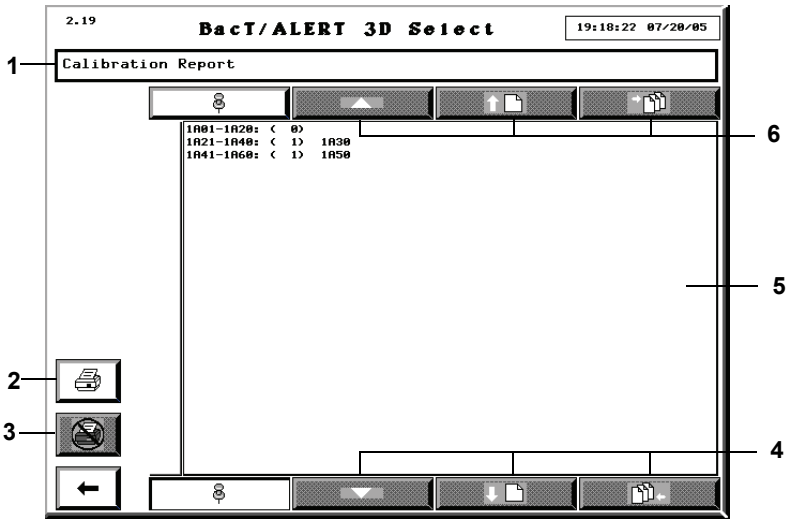


Figure 6-16: Cell Calibration Report Screen

1 — Report Header
2 — Print Button
3 — Cancel Print Button
4 — Scroll Down Buttons
5 — View Window
6 — Scroll Up Buttons

4) Enter a *report title* in the **Report Header** field (a maximum of 64 alphanumeric characters).

5) To scroll up a line, page, or home, click the appropriate **Scroll Up** buttons.

6) To scroll down a line, page, or end, click the appropriate **Scroll Down** buttons.

Note: *The **Scroll Up/Down** buttons are disabled if there are no available lines/ pages in the indicated direction.*

7) To print the report, click the **Print** button.

Note: *The **Print** buttons are only available if a printer is configured for the system. To configure a printer for the system, contact your local bioMérieux Representative.*

8) When the report begins printing:

- The **Print** button is disabled while a report is printing. The operator may, however, view and scroll through the displayed report.
- The **Exit** button is disabled while a report is printing.
- The **Cancel Print** button ( ) replaces the **Print** button. Click the **Cancel Print** button to stop the printing.

9) Click the **Previous Screen** button to return to the Report Selection screen.

The report content is displayed in the View window and contains the following features:

- The ID of each installed rack.
- The number of cells out of calibration for the rack just identified.
- The ID of the cells that are out of calibration for the rack just identified.

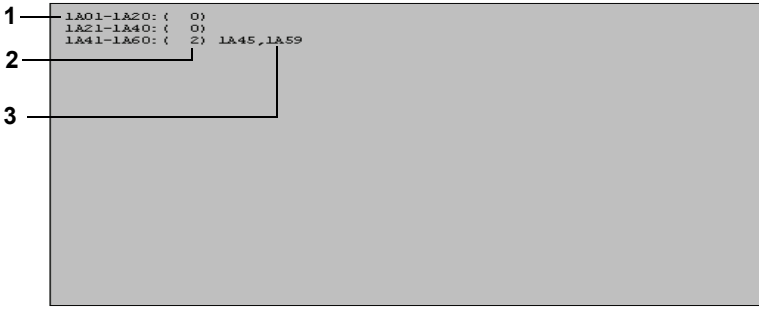


Figure 6-17: View Window

1 — Rack ID
2 — Number of Cells out of Calibration for this Rack
3 — ID of Cells out of Calibration

Note: *Always print a calibration report prior to calibrating any cells. Then print a report after calibrating the cells. This will ensure that a record is obtained that shows corrective action was taken.*

Viewing and Printing Calibration History

The Calibration History screen shows you when cells went in and out of calibration.

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) From the Setup screen, click the **Report** button ( ).

   The Report Selection screen appears.

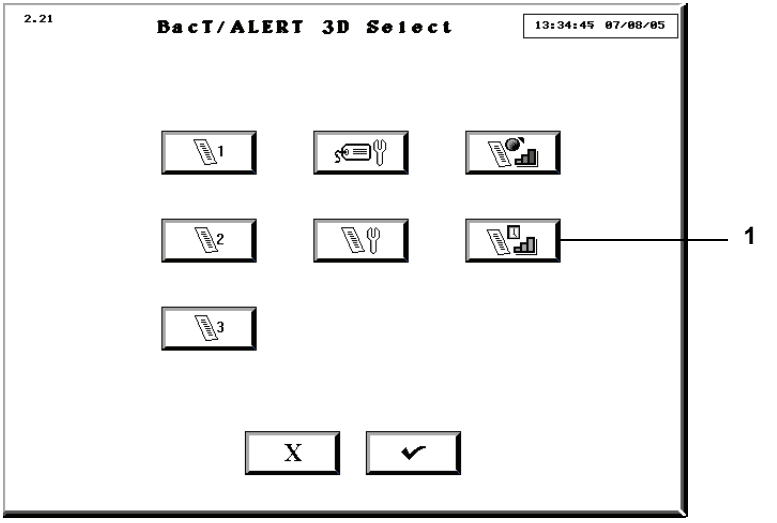


Figure 6-18: Report Selection Screen

1 — Calibration History Button

3) Click the **Calibration History** button ( ).

The Calibration History screen appears.

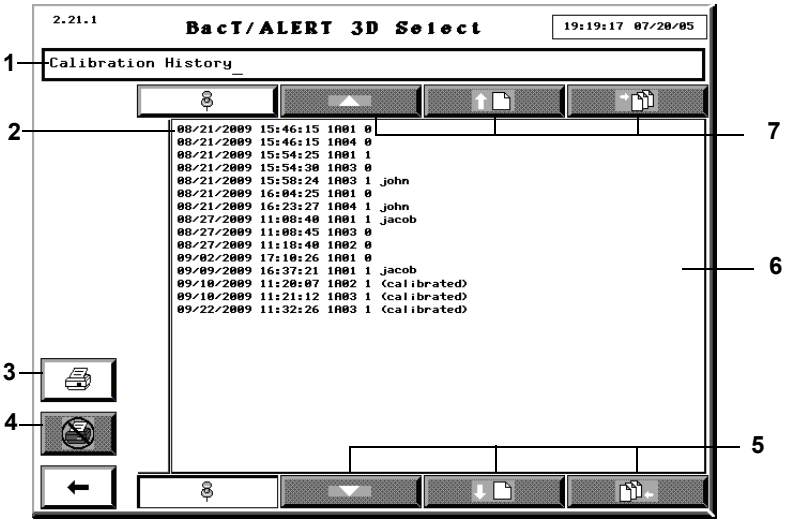


Figure 6-19: Calibration History Screen

1 — Report Header

2 — Date, Time, Cell Location, and Cell Status

3 — Print Button

4 — Cancel Print Button

5 — Scroll Down Buttons

6 — View Window

7 — Scroll Up Buttons

The report content is displayed in the View window and contains the following features:

- The date and time event occurred (in or out of calibration)
- Cell Location
- Cell Status (**0** = when cell falls out of calibration/**1** = when cell goes back in calibration

If the cell is manually calibrated, **(calibrated)** is displayed to the right of the **1**. Or, if in 21 CFR Part 11 mode, the *user name* is displayed.

Note: *There is nothing displayed to the right of the **1** or **0** if the cell falls out of calibration, or drifts back into calibration.*

Note: *The last 10,000 calibration events are saved in the calibration history. When the maximum number of events is reached, the oldest events are overwritten.*

4) Enter a *report title* in the **Report Header** field (a maximum of 65 alphanumeric characters).

   This title appears at the top of the report when printed.

5) To scroll up a line, page, or home, click the appropriate **Scroll Up** buttons.

6) To scroll down a line, page, or end, click the appropriate **Scroll Down** buttons.

Note: *The **Scroll Up/Down** buttons are disabled if there are no available lines/ pages in the indicated direction.*

7) To print the report, click the **Print** button.

Note: *The print buttons are only available if a printer is configured for the system. To configure a printer for the system, contact your local bioMérieux Representative.*

8) When the report begins printing:

   - The **Print** button is disabled while a report is printing. You may, however, view and scroll through the displayed report.
   - The **Exit** button is disabled while a report is printing.
   - The **Cancel Print** button ( ) is enabled. Click the **Cancel Print** button to stop the printing as soon as the print queue empties.

9) Click the **Previous Screen** button to return to the Report Selection screen.

SYSTEM MAINTENANCE 7

About This Chapter

This chapter provides you with procedures on how to perform hardware and software maintenance on the BacT/ALERT® 3D 60 instrument.

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Using the Keyboard in Place of the Mouse • 7-6

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Hardware Maintenance

Preventative Maintenance

Routine BacT/ALERT® 3D 60 preventive maintenance is determined by your bioMérieux service program. There is no additional requirement for customer performed preventive maintenance. Contact your local bioMérieux Representative to schedule periodic service.

Safety Precautions and Procedures

The design of the BacT/ALERT® 3D 60 provides several features in the interest of operator and laboratory safety.

- All glass bioMérieux BacT/ALERT® media bottles are manufactured with a polyethylene safety sleeve to limit the effects of damage to a bottle.
- All bioMérieux BacT/ALERT® media bottles are non-venting to minimize the risk of needle sticks.
- Each bottle cell within the BacT/ALERT® 3D 60 Instrument is sealed to help contain and minimize effects of liquid leakage.
- The circulating fans within the Instrument turn off whenever the door is open, minimizing airflow and the potential for aerosols.
- To reduce the chance for binding a heavily overlabeled bottle, Instrument cells are gently tapered and fabricated from a pliable polymer.
- Electrical voltages within the Incubation Chamber are low (approximately 5 volts or less) to minimize potential electrical hazards.
- Should the optimal temperature in the Instrument be set to a point outside the range 35–37°C, a yellow Operator alert will appear on the Calibrate Temperature screen of the Instrument.
- Any mention of bleach refers to the standard 5.25% sodium hypochlorite. A 10% bleach solution would indicate a 1:10 dilution of the standard 5.25% sodium hypochlorite.

WARNING

All spills should be treated as if capable of transmitting disease.

Spill Cleanup

Where appropriate, follow your institution's spill clean up procedures.

WARNING

For spills that might involve *M. tuberculosis*, proper protective equipment should be worn, including HEPA filtered respirator, gloves, eye protection, and a lab coat. In some cases, coveralls or shoe covers should be worn to avoid contaminating street clothing.

1) Gently cover the spill area with a paper towel. Apply a 10% bleach solution or other EPA registered tuberculocidal disinfectant.

2) Using the bleach solution, wet down all surfaces with which the spill may have come in contact.

3) Allow all surfaces adequate contact time with the bleach solution (15–30 minutes) before cleanup.

4) All materials used in the clean up should be treated as biohazardous waste.

Disinfection Procedure for Spills Onto the Instrument

Any blood or test specimen spilled on an instrument should be removed immediately using the following procedure.

WARNING

Protective gloves should always be worn when handling blood, blood components, or blood-contaminated material.

1) Clean the spill from the instrument following your institution's recommended procedure for decontamination or the procedure described in the latest revision of Clinical and Laboratory Standards Institute (CLSI) guideline “Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body fluids, and Tissue“ CLSI Document M29-A.

2) After decontamination, wipe with damp (water only) towel and thoroughly dry.

Disinfection Procedure for Spills Within the Instrument

WARNING

If a spill is detected that might involve *M. tuberculosis*, only persons wearing protective clothing and suitable respiratory protection should remain in the room. Any test specimen spilled in an instrument should be removed immediately and the affected areas decontaminated using the following procedure.

1) Visually inspect the extent of the leakage or spill. Determine if the instrument or any rack is contaminated.

2) Remove the leaking bottle if possible.

Note: *If a bottle becomes lodged in the cell, contact bioMérieux Customer Service. Do not try to dislodge bottle by pulling on the rack.*

3) Unload positive and negative bottles in affected rack(s) (see Unloading Bottles in Chapter 4).

4) Relocate the remaining bottles in the affected rack(s) using the following procedure.

a. From the Main screen, press **Ctrl + F10** to enter a special Bottles Relocation mode. The cell indicator lights will illuminate in the following pattern:

- Cells with bottles are lit continuously.
- Cells available for reloading are unlit.

Note: *Bottles affected by the spill should not be reloaded until they have been decontaminated. Decontaminate the bottles following your institution's recommended procedure for decontamination or the procedure described in the latest revision of CLSI guideline "Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue" CLSI Document M-29A. Click the **Load Bottles** button to reload the decontaminated bottles.*

b. Relocate bottles one at a time into any available cell or unload contaminated bottles.

Note: *When relocating bottles using **Ctrl + F10**, you must unload one bottle from a cell and reload it into the destination cell BEFORE unloading another bottle. This procedure must be done one bottle at a time.*

c. If the **Bottle ID** field for a loaded bottle is blank, be sure to identify the anonymous bottle by scanning the barcode as it is unloaded (see Handling Anonymous Bottles in Chapter 4).

d. When all bottles are relocated or unloaded, click the **Check** button on the Main screen.

CAUTION: When unloading multiple bottles using Ctrl + F10, the bottles must be reloaded before one hour has passed using the normal Load Bottles icon to avoid a subculture event.

5) Disable the affected cell(s) or rack(s) (see Enabling and Disabling Racks and Cells on page 7-13).

6) If an affected cell contains a large amount of liquid, carefully aspirate it using a pipette or similar device and dispose of it in an appropriate biohazardous waste container.

7) If the spill is confined to one or a few cells of one rack, the affected cells may be cleaned and disinfected with a 10% bleach solution, using the following procedure:

CAUTION: Do not expose the cell or rack to the bleach solution for an extended period. 10% bleach is the ONLY disinfectant that has been validated for use with the cells. DO NOT use a different disinfectant or a bleach solution stronger than 10% or damage to cell components may occur.

a. Insert absorbent material, such as gauze, into the cell to remove any remaining fluid. Carefully remove and discard the gauze in a biohazardous waste container.

b. Wipe out the interior of the cell with gauze soaked with 10% bleach solution and discard in a biohazardous waste container.

c. Insert several layers of gauze saturated with a 10% bleach solution into the cell and let sit for 15–30 minutes to decontaminate. The gauze should be soaked to the point of saturation but not so wet that liquid drips out of the cell.

d. Remove and discard the gauze in a biohazardous waste container.

e. Wipe the interior of the cell with gauze soaked in distilled water to rinse.

f. Allow the cell to air dry.

g. Calibrate the cell. If the cell passes calibration, enable the cell (see Enabling and Disabling Racks and Cells on page 7-13).

8) If the cell fails calibration or there is visible blood residue still present in the cell; particularly on the bottom, clean as follows:

a. Insert absorbent material, such as gauze, into the cell to remove any remaining fluid. Carefully remove and discard the gauze in a biohazardous waste container.

b. Rinse with 10% bleach solution, then distilled water and let air dry.

c. Calibrate the cell. If the cell still cannot be calibrated, disable the cell and insert an orange cell plug to indicate the cell should not be used.

9) For more extensive spills, it may be necessary to remove one or more racks. To gain access to internal instrument surfaces, remove all three racks (contact your bioMérieux Representative).

Note: *Decontaminate bottles, cells, and racks, following your institution's recommended procedure for decontamination or the procedure described in the latest revision of CLSI guideline "Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue" CLSI Document M-29A.*

Using the Keyboard in Place of the Mouse

Normally, the mouse and monitor are used to make selections and enter data. The keyboard provides an alternate method as follows.

- Items on a screen may be selected using the **Tab** key. The selected item is identified by a contrasting color outlining the item.
- Pressing the **Enter** key initiates the function for the selected item.
- For menus that require entry of a numeric password, numeric keys can be used in place of clicking on the screen. The **1** to **4** keys are used to enter the password value. The **5** key is used in place of clicking the **Key Symbol** button.
- Scroll buttons are selected using the **Tab** key. Once the desired scroll button is selected, use the **>** or **<** keys to select the **Up** or **Down** scroll arrow.

Function keys can be used to invoke the following functions:

Alt + F5	Clears Instrument Fault Code 80 faults for all cells at the same time. This function only works while the Setup screen is displayed and after a password is entered.

Ctrl + F1 Activates a special unload mode. This identifies bottles that are loaded in cells that are non-operational. When the door is opened, the cell indicator lights will light for those bottles in non-operational cells. Cells with rapidly flashing cell indicator lights are disabled or unusable.

In this mode, the Instrument automatically activates the Unload Bottles function. Bottles can be removed from the indicated cells one at a time and moved to unusable cells whose cell indicator light will be off. This function only works while the Main screen is displayed.

Ctrl + F2 Activates a special unload mode. This identifies cells out of calibration. All such cells are identified whether they are loaded or not. When the door is opened, the cell indicator lights will light for cells out of calibration. This function only works while the Main screen is displayed.

Ctrl + F3 Activates a special unload mode. This identifies bottles which have an Instrument Fault Code 80. When the door is opened, the cell indicator lights will light for those bottles with the 80 instrument fault. In this mode, the instrument automatically activates the Unload Bottles function. This function only works while the Main screen is displayed.

Ctrl + F10 Activates a special bottle relocation mode. This identifies all currently loaded bottles regardless of their test status. When the door is opened, the cell indicator lights will light for the loaded cells. Cells available for reloading are unlit. This function only works while the Main screen is displayed.

UPS On/Off Button Location

The UPS for the Instrument is external. The **On/Off** button is located at the front of the UPS.

Instrument Reboot/Shutdown

The following situations require the Instrument to be turned off or rebooted.

- Anticipated power outage.
- Moving a system to a new location.
- Fixing an unresponsive mouse, monitor, or keyboard.

Note: *Before rebooting the Instrument, always perform a system backup (see Initiating Manual Backup in Chapter 6). Do not proceed with the reboot until the* ***Backup in Progress*** *icon no longer displays.*

Note: *Call your local bioMérieux Customer Service Representative prior to rebooting to clear an error condition.*

Perform in sequence as many of Methods 1 – 4 as are required to power down or reboot the system.

CAUTION: Contact your local bioMérieux Customer Service prior to using Method 4.

Shutdown Method 1

1) On the keyboard, press each key in the order listed: **Esc Y E S**.

2) Wait for the software to exit to a black screen with a C:\ > prompt.

To reboot the BacT/ALERT® 3D 60, click each keyboard key in the order listed, keeping each key depressed. Then simultaneously release all three keys: **Ctrl** + **Alt** + **Delete**.

or

Alternately, to turn Off the power for the Instrument and the UPS, see Method 4.

Shutdown Method 2

1) Click the **Right Arrow** button to advance to the Setup screen.

Note: *If the system is unresponsive, proceed to Method 4.*

2) Enter the Software Exit Password **24313124**.

3) The password entered is accepted by clicking the **Key Symbol** button at the right end of the row of **Password Entry** buttons.

4) After the Software Exit Password is correctly entered, the **Padlock** icon changes to the full open position. The **Exit Software** button will become visible and will be the only active button on the Setup screen.

5) Click the **Exit Software** button ( ).

6) Wait for the C:\> prompt to appear on a black screen.

To reboot the BacT/ALERT® 3D 60, click each keyboard key in the order listed, keeping each key depressed. Then simultaneously release all three keys: **Ctrl** + **Alt** + **Delete**.

or

Alternately, to turn Off the power for the Instrument and the UPS, see Method 4.

Shutdown Method 3

1) Press each keyboard key in the order listed, keeping each key depressed and then simultaneously releasing all four keys: **Ctrl** + **Alt** + **Shift** + **2**.

Note: *If keyboard is unresponsive, proceed to Method 4.*

2) Wait for the C:\> prompt to appear on a black screen.

   To reboot the program, click each keyboard key in the order listed keeping each key depressed and then simultaneously releasing all three keys: **Ctrl** + **Alt** + **Delete**.

   or

   Alternately, to turn Off the power for the Instrument and the UPS, see Method 4.

Shutdown Method 4

CAUTION: Contact your local bioMérieux Customer Service Representative prior to using Method 4.

1) Turn Off the Instrument Power Switch. This switch is located in the back, just above the power cord entry.

2) Click the UPS **On/Off** button once to turn Off the power to the UPS (see UPS On/Off Button Location on page 7-7).

Instrument Startup

1) Turn On the Instrument Power Switch. This switch is located in the lower left corner facing the back of the Instrument.

2) Click the UPS **On/Off** button once to turn On the power to the UPS (see UPS On/Off Button Location on page 7-7).

Software Maintenance

Introduction

The following procedures describe maintenance procedures that are performed using the software. These procedures are available regardless of software configuration, but should not need to be performed on a daily basis. The functions described are:

- Restarting the Incubation Chamber (see Restarting the Incubation Chamber on page 7-10).
- Setting the date/time and selecting date/time formats (see Setting and Formatting the System Date and Time on page 7-11).
- Enabling and disabling racks and cells (see Enabling and Disabling Racks and Cells on page 7-13).
- Checking the temperature, setting the optimal temperature, and calibrating the temperature of the Instrument (see Adjusting an Instrument's Temperature on page 7-15).
- Calibrating and viewing readings of cells (see Calibrating an Instrument Cell on page 7-18).
- Viewing Incubation Chamber information (see Viewing Incubation Chamber Information on page 7-22).

Restarting the Incubation Chamber

Perform the following to restart an Incubation Chamber without using the power switch in the case of a communication problem.

1) Click the **Instrument** icon on the Main screen (see Figure 4-1).

The View Cell Status screen appears.

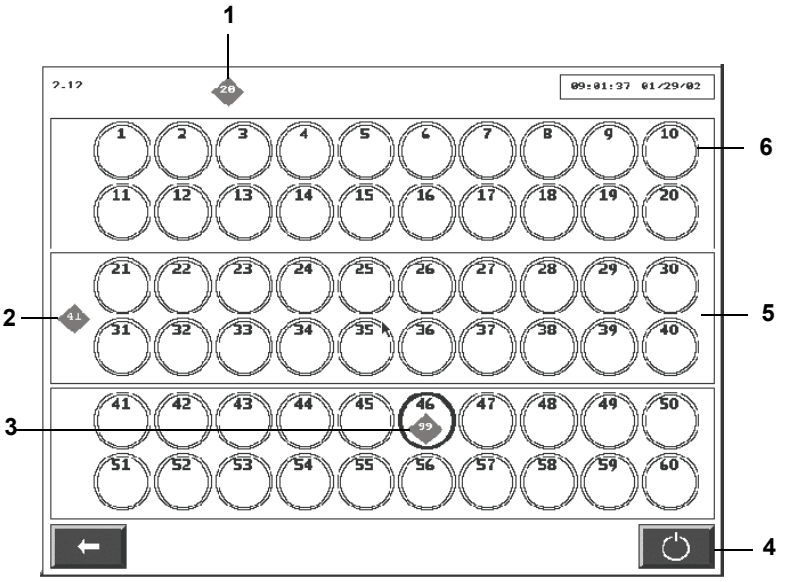


Figure 7-1: View Cell Status Screen

1 — Door Fault Code
2 — Rack Fault Code
3 — Cell Fault Code
4 — Restart Incubation Chamber Button
5 — Rack
6 — Cell

2) Click the **Restart Incubation Chamber** button.

Note: *It is normal for instrument status code 710 to display briefly.*

Setting and Formatting the System Date and Time

Note: *The date and time are set at installation, but the system does not adjust automatically for daylight savings time.*

CAUTION: DO NOT change the date without first contacting your local bioMérieux Customer Service Representative.

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) From the Setup screen, click the **Set Date/Time** button ( ).

The Set Date/Time screen overlays and disables the Setup screen.

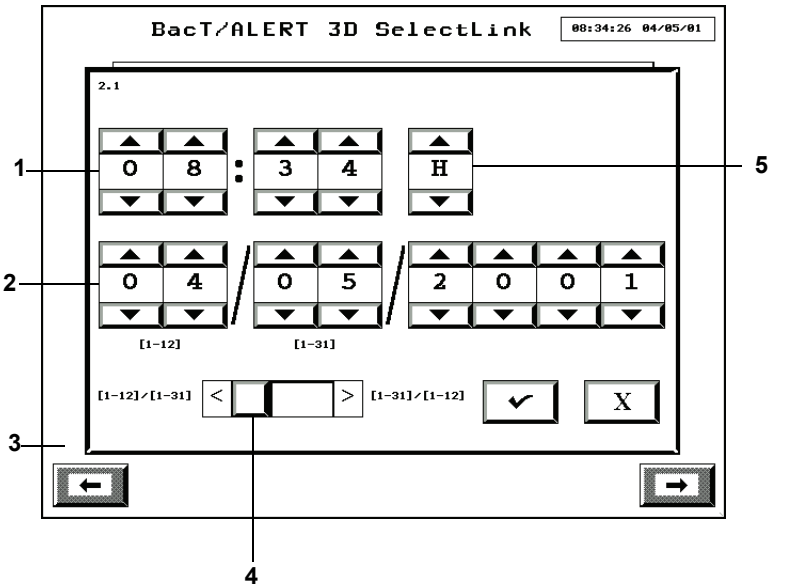


Figure 7-2: Set Date/Time Screen

1 — Set Time Scroll Buttons

2 — Set Date Scroll Buttons

3 — Setup Screen (Disabled)

4 — Date Format Slidebar Switch

5 — Time Format Scroll Button

3) Adjust the time using the **Set Time** scroll buttons. The scroll buttons to the left of the colon determine the hour, and the scroll buttons to the right of the colon determine the minutes.

4) Adjust the time format using the **Time Format** scroll button. When the scroll button is set to **AM** or **PM**, a 12-hour format is employed. If **H** is selected, the 24-hour format will apply.

5) Adjust the date using the **Set Date** scroll buttons. The two scroll bars used to enter the month have [1–12] displayed below them, and the two scroll bars used to enter the day have [1–31] displayed below them. The order of these will depend on the date format selection.

6) Adjust the date format using the **Date Format** slidebar switch. The left option is MM/DD/YY and the right option is DD/MM/YY.

Note: *The date format selected applies to the current date/time display at the top of each screen, to all fields that display a date and/or time, and to reports where available.*

7) Click the **Check** button to accept the changes, or click the **Cancel** button to retain the original settings.

8) The system returns to the Setup screen.

Enabling and Disabling Racks and Cells

1) Before disabling a rack or cell, make certain there are no bottles in the part to be disabled (see Relocating Bottles on page 7-14).

2) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

3) Click the **Enable/Disable Rack or Cell** button ( ).

The Enable/Disable Rack or Cell screen overlays and disables the Setup screen.

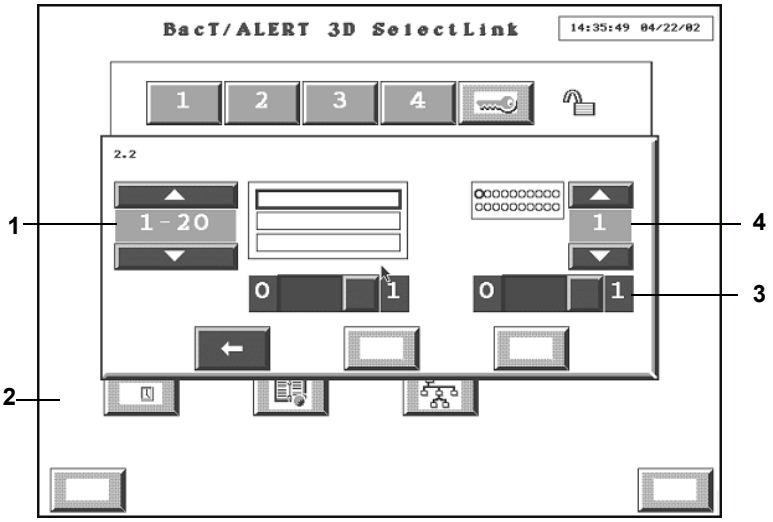


Figure 7-3: Enable/Disable Rack or Cell Screen

1 — Rack Scroll Button
2 — Setup Screen (Disabled)
3 — Enable/Disable Slidebar Switch
4 — Cell Scroll Button

4) To enable/disable an entire rack:

   a. Select the Rack desired (1–20, 21–40, or 41–60) using the **Rack** scroll button.

   b. Set the **Enable/Disable** slidebar switch below the Rack icon to enable (**1**) or disable (**0**).

   c. Go to Step 6.

Note: *If a rack is disabled, then the cells in that rack are disabled and turn gray; however, disabling a rack does not change the current setting of each of the slidebars for those cells.*

5) To enable/disable a cell:

   a. Select the Rack (1–20, 21–40, or 41–60) that holds the cell using the **Rack** scroll button.

   b. Select the Cell desired (1–20) using the **Cell** scroll button.

   c. Set the Enable/Disable slidebar switch below the Cell icon to enable (**1**) or disable (**0**).

6) Click the **Check** button to accept change(s), or the **Cancel** button to return previous settings.

7) Click the **Previous Screen** button to return to the Setup screen.

Relocating Bottles

In certain situations (ex. before disabling a rack), it may be necessary to move bottle(s) into another available cell or rack.

CAUTION: When unloading multiple bottles using Ctrl + F10, the bottles must be reloaded before one hour has passed using the normal Load Bottles icon to avoid a subculture event.

1) From the Main screen, press **Ctrl** + **F10** to enter a special Bottles Relocation mode. The cell indicator lights will illuminate in the following pattern:

   • Cells with bottles loaded are lit continuously.

   • Cells available for reloading remain unlit.

Note: *When relocating bottles using **Ctrl + F10**, you must unload one bottle from a cell and reload it into the destination cell BEFORE unloading another bottle. This procedure must be done one bottle at a time.*

2) Pull bottles out one at a time and reload one at a time into any available cell.

3) If the **Bottle ID** field for a loaded bottle is blank, be sure to identify the anonymous bottle by scanning the barcode as they are unloaded (see Handling Anonymous Bottles in Chapter 4).

4) When all bottles are relocated, click the **Check** button on the Main screen (see Figure 4-1).

Adjusting an Instrument's Temperature

The following procedures describe:

- How to check an Instrument's temperature.
- How to set an Instrument's optimal temperature setting.
- How to calibrate an Instrument's temperature.

Checking an Instrument's Temperature

Each Instrument includes an NIST-traceable Reference Thermometer located on the Rack Cable Cover (see Figure 7-4). This thermometer is the reference used to calibrate the temperature.

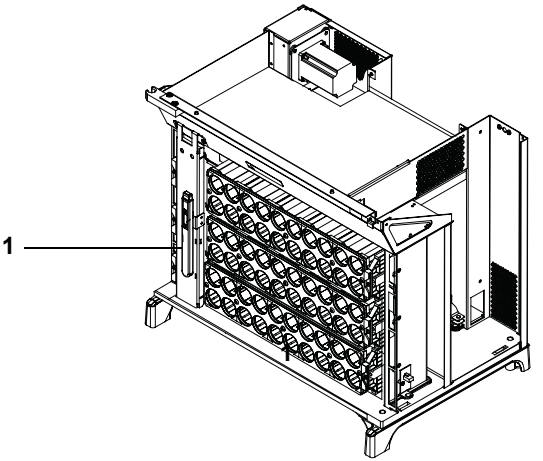


Figure 7-4: Reference Thermometer

1 — Thermometer Location

Note: *The thermometer should be periodically validated according to your current protocol.*

Before opening the door to take a reading with this thermometer, verify that the temperature is stable by doing the following:

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the **Calibrate Instrument Temperature** button ( ).The Calibrate Instrument Temperature screen overlays and disables the Setup screen.

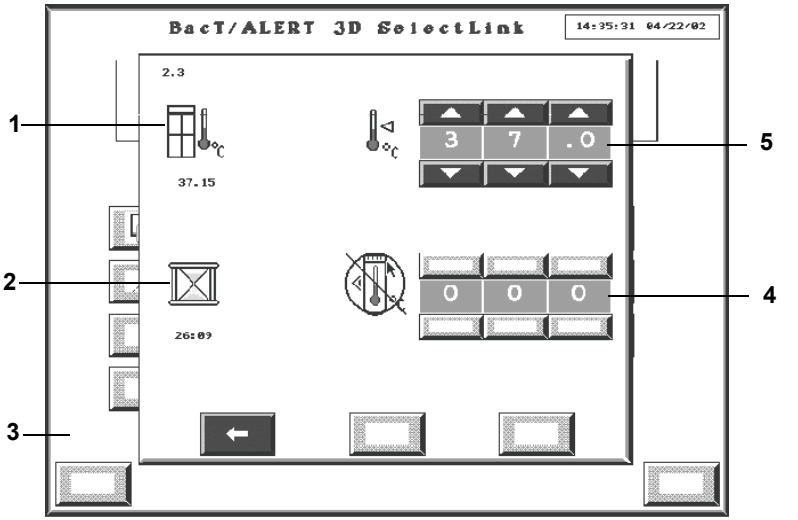


Figure 7-5: Calibrate Instrument Temperature Screen

1 — Internal Air Temp Indicator
2 — Time Remaining Until Stable Indicator
3 — Setup Screen (Disabled)
4 — Actual Temp Scroll Buttons
5 — Optimal Temp Scroll Buttons

3) Observe the icon to the left of the **Actual Temp** scroll buttons.

Indicates the temperature is not stable. Do not read the Reference Thermometer at this time.

Indicates the temperature is nearly stable. The time underneath the hourglass is the number of minutes: seconds remaining until stable temperature is reached.

Indicates the temperature is stable. The Reference Thermometer may be read.

4) Read the temperature once the temperature is stable.

5) Close the door immediately after taking the reading.

Setting the Optimal Temperature for an Instrument

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the **Calibrate Instrument Temperature** button ( ).

   The Calibrate Instrument Temperature screen overlays and disables the Setup screen (see Figure 7-5).

3) Enter the desired optimal temperature in degrees Centigrade (°C) on the **Optimal Temp** scroll buttons.

Note: *The valid range of values for the optimal temperature of an Instrument is 25.0°C to 45.0°C. However, the usual test range encountered in clinical laboratories is 35°C to 37°C. If a temperature is entered that is outside the range of 35°C to 37°C, a bright yellow icon ( ) is displayed below the scroll button.* ***The lowest temperature the instrument can maintain is 5°C above ambient.***

4) Click the **Check** button to initiate the temperature adjustment, or click the **Cancel** button to retain the previous setting.

5) Click the **Previous Screen** button to return to the Setup screen.

6) Calibrate the Incubation Chamber after the temperature becomes stable (see Checking an Instrument's Temperature on page 7-15).

Calibrating an Instrument's Temperature

Temperature calibration is required:

- Anytime the optimal (setpoint) temperature is changed.

- Any time the periodic check of the Reference Thermometer reveals that the temperature is more than 0.5°C above or below the setpoint.

1) Check the Instrument's temperature (see Checking an Instrument's Temperature on page 7-15).
2) Enter the temperature from the Reference Thermometer in degrees Centigrade (°C) on the **Actual Temp** scroll buttons (see Figure 7-5).
3) Click the **Check** button to initiate the calibration, or click the **Cancel** button to retain the previous calibration.
4) Click the **Previous Screen** button to return to the Setup screen.
5) Check the temperature when stable to verify the calibration was successful.

Calibrating an Instrument Cell

The following procedures describe how to:

- locate a cell which failed calibration
- view a cell's readings
- calibrate a cell.

Note: It is not necessary to perform routine cell calibration. If a cell fails its automatic internal diagnostic check, Instrument Fault Code 60 appears in the **Instrument** icon on the Main screen.

CAUTION: A cell which has failed the automatic internal diagnostic check no longer records bottle readings and will not be indicated as available when loading bottles. The cell must be calibrated or disabled.

CAUTION: Do not invoke the Calibrate Cell screen unless the cell to be calibrated is empty.

Locating a Cell Which Failed Calibration

1) View the Main screen to locate the Instrument Fault Code 60 in the **Instrument** icon.
2) Locate the cell with the fault (see Viewing Faults in Chapter 4).

Note: *If the cell cannot be calibrated immediately, disable the cell (see Enabling and Disabling Racks and Cells on page 7-13).*

CAUTION: To prevent anonymous loading into the disabled cell, place an orange cell plug into the cell.

Viewing a Cell's Readings and/or Calibrating a Cell

1. If calibrating, print out the Cell Calibration Report (see Viewing and Printing Calibration Data in Chapter 6).
2. If the cell to be calibrated contains a bottle, then relocate it (see Relocating Bottles on page 7-14).
3. Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).
4. Click the **Calibrate Cell** button ( ).

   The Calibrate Cell screen overlays and disables the Setup screen.

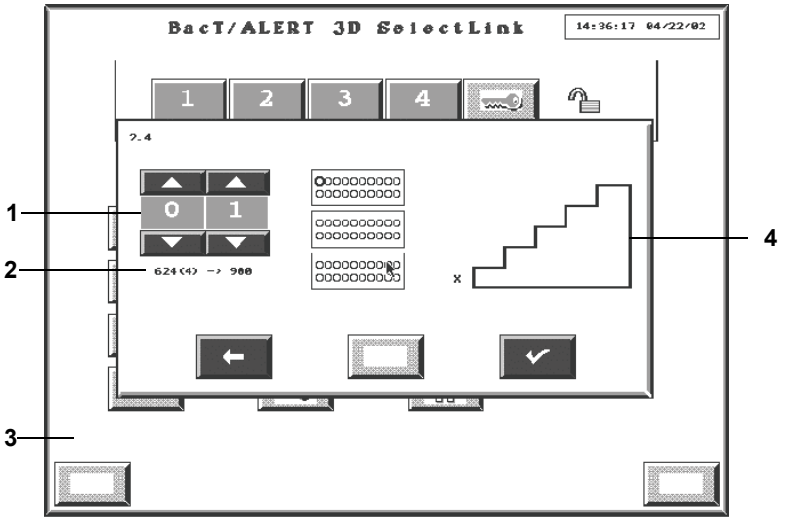
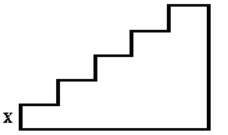


Figure 7-6: Calibrate Cell Screen

1 — Cell Scroll Buttons
2 — Cell Reading Indicator
3 — Setup Screen (Disabled)
4 — Calibration Staircase Icon

5) Select a particular cell to be calibrated by choosing the appropriate cell (1–60) with the **Cell** scroll buttons.

The first screen displays an **X** at the base of the **Calibration Staircase** icon. This prompts the user to verify the cell is empty and the door is closed.



Note: *The **Cell** scroll buttons will be grayed-out and inactive until calibration of the cell is complete.*

To view a cell's reading:

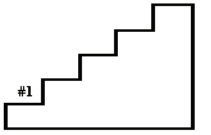
6) The cell's readings can now be read below the **Cell** scroll buttons. The first set of numbers represents the uncalibrated reading and the number to the right of the arrow represents the calibrated readings.

Note: *If an Incubation Chamber is not configured properly or is not responding, asterisks will replace the digits on the screen.*

If you would like to calibrate a cell, proceed to next step.

7) Click the **Check** button.

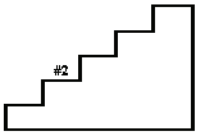
The cell indicator light of the cell selected for calibration is now illuminated and **#1** appears above the first step of the **Calibration Staircase** icon.



8) Insert Standard Number One into the selected cell without touching the ends of the calibration standard as calibration could be affected. (A single ring around the end of the reflectance standard identifies Standard #1).

9) Click the **Check** button.

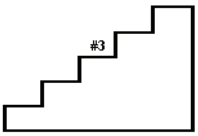
A **#2** appears above the second step of the **Calibration Staircase** icon.



10) Insert Standard Number Two into the selected cell. (Two rings around the end of the reflectance standard identifies Standard #2).

11) Click the **Check** button.

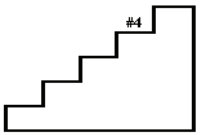
A **#3** appears above the third step of the **Calibration Staircase** icon.



12) Insert Standard Number Three into the selected cell. (Three rings around the end of the reflectance standard identifies Standard #3).

13) Click the **Check** button.

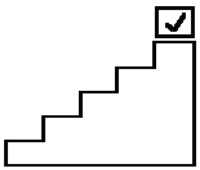
A **#4** appears above the fourth step of the **Calibration Staircase** icon.



14) Insert Standard Number Four into the selected cell. (Four rings around the end of the reflectance standard identifies Standard #4).

15) Click the **Check** button.

16) If a check mark appears at the top of the **Calibration Staircase** icon, then the calibration of the cell was successful. Remove Standard Number Four and click the **Check** button to save the new calibration values.



17) If instrument fault code 60 appears at the top of the **Calibration Staircase** icon, then the calibration of the cell is unsuccessful. Click the **Cancel** button and follow Step 4 through Step 14 to recalibrate the cell.

Note: *The cell is not automatically enabled after calibration is completed successfully. If the cell was previously disabled, it must be enabled (see Enabling and Disabling Racks and Cells on page 7-13).*

18) Click the **Previous Screen** button to return to the Setup screen.

Note: *The calibration process can be canceled and any new calibration values discarded by clicking the **Cancel** button at any step during the calibration process.*

19) Print out the Cell Calibration Report (see Viewing and Printing Calibration Data in Chapter 6).

Viewing Incubation Chamber Information

This procedure describes how to locate the following information:

- Serial Numbers
- Hardware Revisions
- Software Revisions

You may be requested to retrieve this information during the course of troubleshooting by your local bioMérieux Representative.

1) Arrow to the Setup screen and enter a valid password to access the function buttons (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) Click the **View Incubation Chamber Information** button ( ).

The View Incubation Chamber Information screen replaces the Setup screen.

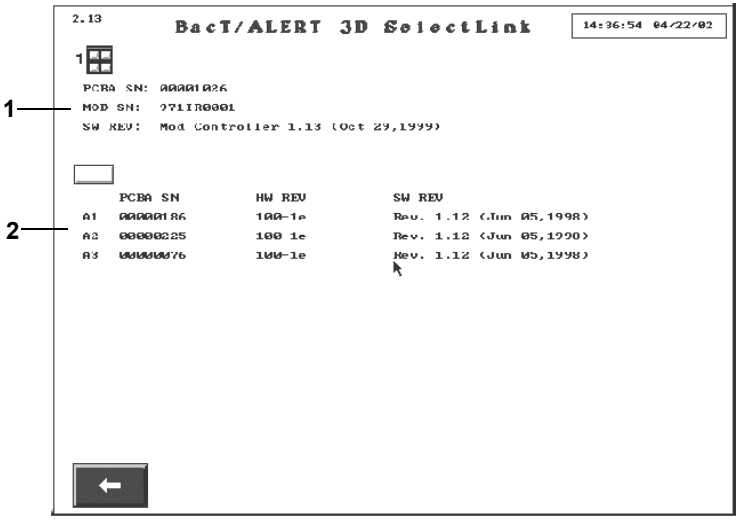


Figure 7-7: View Incubation Chamber Information Screen

1 — Incubation Chamber Information

2 — Rack Information

3) Click the **Previous Screen** button to return to the Setup screen.

SYSTEM TROUBLESHOOTING 8

About This Chapter

This chapter provides you with a description of the different types of instrument fault, instrument status and operator error codes, as well as bottle and user output device problems, that may be encountered when using the instrument. Cause(s) and solutions(s) for each type of fault/error/problem are also listed.

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Bottle Problems • 8-29

User Output Device Problems • 8-29

Introduction

CAUTION: Failure to follow the procedures in this User Manual or failure to attend to fault conditions reported by the instrument within one hour may lead to invalid test results and the need to subculture bottles.

The following codes are discussed in this chapter.

1	39	56	99	923
2	41	57	710	930
3	42	60	800	931
4	43	62	810	932
6	44	71	820	940
10	45	72	901	941
11	46	73	902	942
12	47	74	909	943
14	51	75	910	944
19	52	77	911	945
20	53	78	912	960
21	54	80	913	961
22	55	81	921	

If the problem cannot be corrected using the solutions listed, or a code is displayed that does not appear in this list, call your local bioMérieux Representative.

Fault Codes

Instrument Fault Codes

Instrument Fault Codes appear in the **Instrument** icon. A description of each Instrument Fault Code is provided. The following is an example of an **Instrument** icon with Instrument Fault Codes 2, 10, and 20. Fault codes are displayed on the particular components where the errors are located.

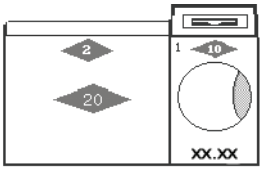

Figure 8-1: Instrument Icon with Fault Codes

Note: *Locate specific bottles with fault by clicking the Incubation Chamber on the **Instrument** icon on the Main screen to display the View Cell Status screen.*

CAUTION: Fault codes referring to loss of incubator temperature may adversely affect bottle testing and should be addressed immediately.

#1	POWER FAULT IN INCUBATION CHAMBER **Cause:** Fuse has been blown. **Solution:** Contact bioMérieux.
#2	COMMUNICATION LOST WITH INCUBATION CHAMBER **Cause:** Internal cables may be loose, or hardware problem. **Solution:** Contact bioMérieux.

#3 Incubation Chamber Temperature Is Too High

Background Information: The optimal temperature (setpoint) and actual Chamber temperature are not equilibrated. Two temperature sensors, one in the supply side of the air plenum, and one in the cold air return, are used to monitor the Incubation or Combination Module temperature. This error will occur if there is a ± 2°C change from the setpoint measured at the sensors for approximately one minute (5 or more readings are taken every 10 seconds). Five or more readings out of range are required to report this error. Common causes for this error are: ambient room temperature is too high, temperature calibration was not performed correctly, or defective hardware (ex. MOD SIG, temperature sensors, or relay).

Cause: The Instrument optimal temperature (setpoint) has been changed and has not yet equilibrated at the new temperature.

Solution: Wait for the chamber temperature to equilibrate.

Cause: Bottle testing may be adversely affected due to one of the following reasons:

- Hardware fault with the ModSig Board.
- Hardware fault with the Solid State Relays that energize the heater.
- Faulty temperature sensors.

Solution: Contact bioMérieux immediately.

#4 Incubation Chamber Temperature Is Too Low

Background Information: The optimal temperature (setpoint) and actual Chamber temperature are not equilibrated. Two temperature sensors, one in the supply side of the air plenum, and one in the cold air return, are used to monitor the Incubation or Combination Module temperature. This error will occur if there is a ± 2°C change from the setpoint measured at the sensors for approximately one minute (5 or more readings are taken every 10 seconds). Five or more readings out of range are required to report this error. Common causes for this error are drawer left open, setpoint changed and the module has not yet equilibrated at the new temperature, drawer switch misaligned, defective hardware (ex. MOD SIG, temperature sensors, relay, cutoff switch tripped, or heater element).

Cause: The Instrument optimal temperature (setpoint) has been changed and the chamber has not yet equilibrated at the new temperature.

Solution: Wait until Instrument temperature equilibrates.

Cause: The door has been left open or ajar for an extended period.

Solution: Make sure the door closes tightly and allow the chamber temperature one hour to equilibrate.

Cause: Bottle testing may be adversely affected due to one of the following reasons:

- Hardware fault with the ModSig Board.
- Hardware fault with the Solid State Relays that energize the heater.
- Faulty temperature sensors.

Solution: Call bioMérieux immediately.

#6 AGITATION STEPPER MOTOR FAULT

Cause: Agitation Stepper Motor has reported a fault.

Solution: Call bioMérieux.

#10 INSTRUMENT POWER FAULT

Cause: The Instrument is not receiving AC power.

Solution:

1. Ensure AC power source is adequate or connect to an alternate power source.
2. The Instrument runs on UPS power for 1 minute. If AC power is not restored during this time, the Instrument and UPS turn Off. When AC power is restored the Instrument will automatically reboot.
3. If power is not restored within an hour, it may be necessary to subculture bottles.

CAUTION – Do not load or unload bottles until power is restored.

#11 INSUFFICIENT CHARGE IN UPS

Cause: The UPS battery is low.

Solution: Call bioMérieux.

#12 LIS COMMUNICATION FAULT

Cause: The LIS is not responding to the Instrument.

Solution: Check the LIS. The fault automatically goes away when communication with the LIS resumes.

	Cause: The message from the Instrument is not reaching the LIS. **Solution:** Check the cable connections between the Instrument and the LIS.
#14	SYSTEM AUTOMATICALLY REBOOTED
	Cause: Unresponsive state detected in the software. **Solution:** Call bioMérieux immediately. System performance may be compromised.
#19	SOFTWARE EXCEPTION
	Cause: A software exception has occurred. **Solution:** Call bioMérieux immediately. System performance may be compromised.
#20	DOOR OPEN FOR TOO LONG
	Cause: The door has been left open or ajar for an extended period. **Solution:** Make sure door is tightly closed.
	Cause: Door sensors have failed or become misaligned. **Solution:** Call bioMérieux.
	Cause: Fault in the ModSig board. **Solution:** Call bioMérieux.
#21	AGITATION FAILURE
	Cause: Mechanical failure in the agitation linkage. **Solution:** Call bioMérieux.
	Cause: Agitation motor either disconnected or inoperative. **Solution:** Call bioMérieux.
	Cause: Fault in bottom rack. **Solution:** Call bioMérieux.
#22	UNEXPECTED AGITATION
	Cause: Instrument not configured properly. **Solution:** Call bioMérieux.

#39	RACK TEMPERATURE FAULT
	Background Information: The temperature in a specific rack has changed beyond the setpoint (high or low). Two temperature sensors, one at each end of the bottle rack, are polled for the input signals. This fault code was added as an early warning system requiring the user to observe the system for temperature-related issues. This error will occur if there is a ± 4°C change from the setpoint measured at the bottle racks for more than 60 minutes (six readings are taken every 10 minutes). Six or more readings out of range are required to report this error. Typically, this error is seen after bottle loading or unloading events. The change in thermal mass takes the BacT/ALERT® 3D system several minutes to readjust. If the temperature is high, bottle relocation is required and the defective hardware is suspected (for example: temperature sensor). If the temperature is low, ensure that the drawers are closed and monitor the temperature for the next 30 to 40 minutes. If the fault code does not clear, bottle relocation is required and defective hardware is suspected (ex. MOD SIG, temperature sensors, relay, cutoff switch tripped, or heater element).
	Cause: The door has been left ajar for an extended period or there is a system failure. **Solution:** Perform the following procedure: 1. Check the temperature in the Incubation Chamber. 2. If the temperature is high, there is a system failure. Leave the door open so the bottles will not overheat and call bioMérieux. 3. If the temperature is low, make sure the door is completely closed and wait 30 minutes to see if the fault goes away. If the fault does not go away, call bioMérieux.
#41 - 47	RACK(S) X NOT RESPONDING
	Cause: Faulty rack controller or rack interface cable(s). **Solution:** Call bioMérieux.
#51 - 57	RACK HARDWARE FAILURE
	Cause: Faulty Rack printed circuit board. **Solution:** Call bioMérieux.

#60 CELL FAILED QC

Cause: A cell failed the automatic internal diagnostic check.

Solution: Perform the following procedure:

1. Identify the cell that failed the QC using the View Cell Status screen.
2. Inspect the cell for debris and remove or clean, if necessary.
3. Calibrate (see Calibrating an Instrument Cell in Chapter 7). Get corrected Calibration Report, if necessary.
4. If calibration cannot be performed at this time, or if a cell fails to calibrate, disable cell, and insert an orange cell plug in the disabled cell.
5. Call bioMérieux if cell calibration is unsuccessful.

#62 ERRONEOUS CELL LOAD STATUS REPORTED

Cause: A cell is out of calibration.

Solution: Use the View Cell Status screen (see Viewing Faults in Chapter 4) to locate affected cells. Relocate bottle in affected cells using the following procedure:

1. From the Main screen, press **Ctrl + F10** to enter a special Bottle Relocation mode that allows bottles to be relocated. The cell indicator lights will illuminate in the following pattern:
   - Cells with bottles are lit continuously.
   - Cells available for reloading are unlit.
2. Pull bottles out one at a time and reload one at a time into any available cell.
3. If the bottle is anonymous (the **Bottle ID** field is blank), then enter the *bottle ID* (see Text/Data Entry in Chapter 4). When all bottles are unloaded, click the **Check** button on the Main screen.
4. Attempt to calibrate the cell (see Calibrating an Instrument Cell in Chapter 7). Get corrected Calibration Report if necessary.
5. If the calibration fails, then disable the cell (see Enabling and Disabling Racks and Cells in Chapter 7).
   - Insert an orange cell plug into the disabled cell.
   - Call bioMérieux.

Note - *Call bioMérieux if error occurs with numerous cells (it could be a faulty rack controller).*

#71 Invalid Time Stamp

Cause: Hardware failure involving the real time clock.

CAUTION – Bottle readings are not processed while the fault is present.

Solution: Call bioMérieux.

#72 Invalid Calculation Data

Cause: Hardware failure involving the non-volatile random access memory.

CAUTION – Bottles with fault are flagged positive and bottle readings are not processed while the fault is present.

Solution: Determine how long bottle readings have not been processed by going to the Edit Bottle Detail screen and noting the time of the last bottle reading (see Viewing/Editing Bottle Data in Chapter 5). If the time passed is greater than one hour, bottles must be subcultured.

1. Unload the affected bottle via the Unload Positive Bottle function on the Main screen.
2. Subculture the bottle if necessary.
3. Reload the bottle via the Load Bottle function on the Main screen. The original first loaded date and time is maintained.
4. If the fault code persists, call bioMérieux.

#73 Invalid Method Data

Cause: Important information used for bottle analysis has been corrupted and therefore bottle readings are not being processed. Bottles with fault are flagged positive one hour after the fault code first appears. Bottle readings are not processed while the fault is present.

Solution: Each bottle type uses the same method data. Eventually, all bottles of the same type as the one with the fault will also present the same fault code.

1. Reboot the system (see Instrument Reboot/Shutdown in Chapter 7).
2. Call bioMérieux.

#74 ALGORITHM CHANGE

Cause: An incorrect media type has been previously assigned to a bottle. Bottles with fault are flagged positive and bottle readings are not processed while the fault is present.

Solution: Perform the following procedure:

1. Click the **Unload Positive Bottle** button and unload the affected bottle.
2. Subculture the bottle.
3. Reload the bottle via the Load Bottle function on the Main screen. The original first loaded date and time are maintained.
4. If the fault code persists, call bioMérieux.

#75 BOTTLE DATA CORRUPTED

Cause: The data integrity check has found corrupted bottle data. Bottles with fault are flagged positive and bottle readings are not processed while the fault is present.

Solution: Perform the following procedure:

1. Click the **Unload Positive Bottle** button and unload the affected bottle.
2. Subculture the bottle.
3. Reload the bottle via the Load Bottle function on the Main screen to begin testing of bottle.
4. The original first loaded date and time is replaced with the date and time the bottle is reloaded.
5. The maximum test time is set to the default associated with the bottle type.
6. If desired, the bottle's maximum test time may be shortened so that the bottle will complete testing when expected.
7. If the fault code persists, call bioMérieux.

#77 READING POLYNOMIAL CHANGE

Cause: An incorrect bottle type has been previously assigned to a bottle. Bottles with fault are flagged positive and bottle readings are not processed while the fault is present.

Solution: Perform the following procedure:

1. Click the **Unload Positive Bottle** button and unload the affected bottle.
2. Subculture the bottle.
3. Reload the bottle via the Load Bottle function on the Main screen to restart testing. The original first loaded date and time are maintained.
4. If the fault code persists, call bioMérieux.

#78 INCOMPLETE TEST DATA

Cause: This fault occurs when an identified bottle is reloaded anonymously and later is identified and reloaded in the instrument. The original bottle data cannot be merged with the data collected when the bottle was anonymous and therefore the test data is incomplete. Bottles with fault are flagged positive and bottle readings are not processed while the fault is present.

Solution: Perform the following procedure:

1. Unload bottle with fault via the Unload Positive Bottle function on the Main screen.
2. Subculture the bottle.
3. Reload the bottle via the Load Bottle function on the Main screen to restart testing. The original first loaded date and time are maintained.
4. If the fault code persists, call bioMérieux.

#80 READING GAP DETECTED

Cause: This fault occurs when there is a gap in bottle readings greater than one hour. This situation may occur when the power to the Instrument is lost for more than one hour. It may also occur if a negative-to-date bottle is unloaded, then reloaded more than one hour later.

There are two procedures that can be followed when this fault occurs. It is recommended that you print an Unload report before clearing this fault to ensure that you have a record of all bottles with an 80 fault.

Note - *On the Load, Status and Unload reports, bottles with Instrument Fault Code 80 will be marked on the report with a* ***Gap Detection*** *indicator (**!**) next to the result. If a negative bottle has an Instrument Fault Code 80 while it is unloaded, the* ***Gap Detection*** *indicator will remain on the report (see Viewing and Printing Test Data in Chapter 4).*

Solution 1: This procedure instructs you to unload and subculture each bottle to clear the 80 fault:

1. From the Main screen, press **Ctrl + F3** to enter a special unload mode.
2. Subculture the bottle.
3. Reload the bottle via the Load Bottle function on the Main screen to restart testing.

Solution 2: This procedure allows you to clear 80 faults for each affected bottle without unloading.

WARNING – These bottles must have a terminal subculture performed if their final status is negative.

1. From the Setup screen, enter the system password (see Accessing the Setup Screen in Chapter 4).
2. Press **Alt + F5** to clear all faults at the same time.

#81 BOTTLE LOADED IN CELL DURING QC

Cause: This fault occurs when a bottle is loaded in a cell that has not completed the QC cycle. In this case, the fault is displayed with no other fault on the View Cell Status screen. The QC cycle for a cell is indicated by a white circle on the cell status screen (see Figure 4-4, View Cell Status Screen, on page 4-6). Bottle readings are taken while the fault is present.

Solution: Perform the following procedure:

1. Remove the bottle from the cell that was just loaded.
2. Reload the bottle into an available cell (one which has its cell indicator light lit).

Cause: This fault occurs when a bottle is loaded in a cell that is out of calibration (indicated by Fault Code 60). In this case, Fault Codes 60 and 81 are both displayed on the View Cell Status screen, alternating between the two faults (see Figure 4-4, View Cell Status Screen, on page 4-6). Bottle readings are not taken while Fault Codes 60 and 81 are present at the same time.

Solution 1: Perform the following procedure if this fault is recognized within one hour of loading a bottle.

Note - *To check the time the bottle was loaded, access the Edit Bottle Detail screen (see Figure 5-3, Edit Bottle Detail Screen, on page 5-5).*

1. Remove the bottle from the cell that was just loaded.
2. Reload the bottle into an available cell (one which has its cell indicator light lit).

Solution 2: Perform the following procedure if this fault is recognized more than one hour after loading a bottle, or the time the bottle was loaded cannot be determined on the Edit Bottle Detail screen.

1. Access the View Cell Status screen (see Figure 4-4, View Cell Status Screen, on page 4-6) to view the cell error.
2. If the cell displays Fault Code 81 and does not alternate between Fault Codes 81 and 60, readings have been taken on this bottle. Unload the bottle from the cell and reload the bottle into a functional cell using the Load Bottle function (see Figure 4-6, Main Screen — Load Mode, on page 4-10).
3. If the cell displays an error code that alternates between Fault Codes 81 and 60, then readings have not been taken on this bottle. Unload the bottle and perform a subculture. Reload the bottle into a functional cell using the Load Bottle function (see Figure 4-6, Main Screen — Load Mode, on page 4-10).

WARNING – The bottle must be subcultured.

#99 BOTTLE LOADED IN A NON-OPERATIONAL CELL

Cause: A bottle is currently loaded in either:

- A cell that has been disabled, or the rack in which the cell is located is disabled.
- An enabled cell that is not taking bottle readings because of one of the following faults: 51, 52, 54, 60, or 62.

Bottle readings are not processed in faulty cells.

Solution: Use the Edit Bottle Detail screen to determine when the last bottle reading was successfully processed (see Viewing/Editing Bottle Data in Chapter 5). If less than one hour has passed, it is only necessary to relocate the bottles using the following procedure:

1. From the Main screen, press **Ctrl** + **F1**. This mode identifies cells containing bottles with 99, 51, 52, 54, 60, or 62 faults with a lit cell indicator light.
2. Remove bottles from these cells one at a time, move them to cells whose cell indicator lights are unlit.

Note - *If no bottle(s) are present in the indicated cell, call bioMérieux.*

If more than an hour has passed, unload and subculture the bottle in the faulty cells using the following procedure:

1. From the Main screen, press **Ctrl** + **F10**.
2. Remove a bottle to subculture and scan the bottle ID. Repeat this step for the remaining bottles needing subcultures.
3. Click the **Check** button when done.
4. After subculturing bottles, reload them via the Load Bottle function on the Main screen.

Affected bottles that do not need to be subcultured should be relocated. Relocate bottles.

Note - *If no bottle(s) are present in the indicated cell, call bioMérieux.*

Instrument Status Codes

Instrument Status Codes appear in a separate window on the Main screen and are identified by a 98 in the top left corner. A description of each Instrument Status Code is provided. The following is an example of Instrument Status Code 710.

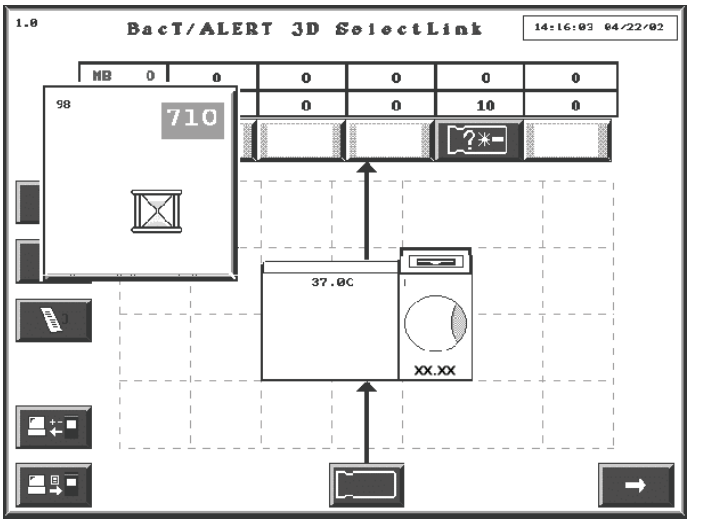

Figure 8-2: Instrument Status Code 710

#710 Incubation Chamber Temporarily Unavailable while Power Up Initialization Takes Place

Cause: Turning On the power of an Instrument or clicking the **Restart Incubation Chamber** button invokes the Power Up screen to appear on the monitor. It is NOT possible to perform any action when the Power Up screen is present.

Solution: No operator action is necessary. The Power Up screen will disappear when the Incubation Chamber is ready. Do NOT load bottles while the Power Up screen is present.

#800 Printer Fault

Cause: The Instrument was unable to print to the printer.

Solution: Check the following:

- The printer is powered on and connected to the Instrument properly.
- The printer has paper.
- The paper is not jammed in the printer.

#810 BACKUP FAILED

Cause: The Instrument was unable to write backup data to the backup media, because the backup media was either missing, defective, or removed while the backup was still in progress.

Solution 1: Perform the following procedure if the backup media is a Zip® drive:

1. Verify that there is a Zip® disk in the Zip® drive and attempt a manual backup (see Initiating Manual Backup in Chapter 6).
2. If this backup fails, insert a new Zip® disk and attempt a manual backup.
3. If this backup fails, call bioMérieux.

Solution 2: Perform the following procedure if the backup media is a USB flash drive:

1. Verify that there is a USB flash drive in the USB port and attempt a manual backup (see Initiating Manual Backup in Chapter 6).
2. If this backup fails, remove the USB flash drive and verify that it is an approved bioMérieux USB flash drive. If it is an approved bioMérieux USB flash drive, re-insert and attempt a manual backup.

   or

   If the USB flash drive is not an approved bioMérieux USB flash drive, then insert a USB Flash drive approved by bioMérieux and attempt a manual backup.
3. If this backup fails, call bioMérieux.

#820 BACKUP MEDIA MISSING OR BACKUP DRIVE FAULT

Cause: Backup media is not fully inserted into the drive.

Solution: Remove backup media and re-insert into the drive.

Cause: Backup media is corrupted.

Solution: Remove backup media and replace with a different backup media.

Cause: Backup drive failure.

Solution: Call bioMérieux.

Cause: Backup media is not an approved bioMérieux device.

Solution: Insert an approved bioMérieux device.

Operator Error Codes

Operator Error Codes appear in a separate window on the Main screen and are identified by a 99 in the top left corner. A description of each Operator Error Code is provided. The following is an example of Operator Error Code 911.

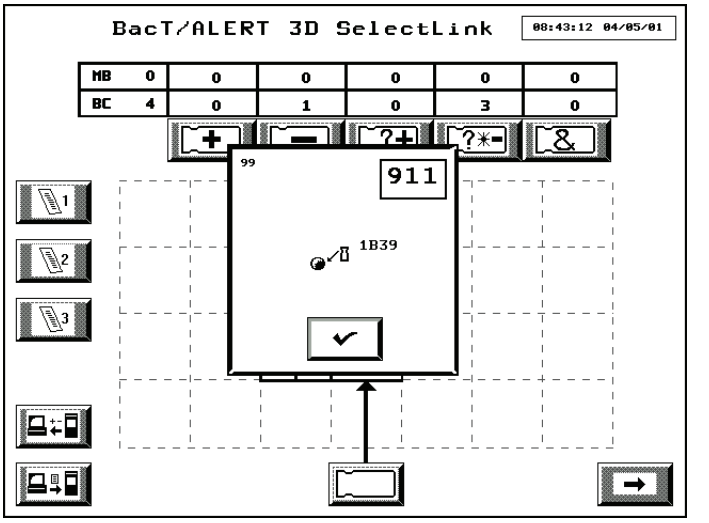

Figure 8-3: Operator Error Code 911

#901 Corrupted Bottle Record has been Selected

Cause: A corrupted bottle record has been selected for the Edit Bottle Detail screen.

Solution: This error will automatically disappear.

1. Note the cell ID for the corrupted bottle record on the Edit Bottle Detail screen.
2. Go to the View Cell Status screen and check the cell for Instrument Fault Code 75.
3. If Fault 75 is present, then follow the procedure provided to correct the problem (see Instrument Fault Code #75 on page 8-10).
4. If error persists, call bioMérieux.

#902 Required Data Missing

Cause: Required data was not entered while loading bottles.

Solution:

1. Remove the bottle from the cell that was just loaded.
2. Complete required fields (see Text/Data Entry in Chapter 4).
3. Reload bottle.

#909 Invalid Cell Load — Cell QC in Process

Cause: This fault occurs when a bottle is loaded in a cell that has not completed the QC cycle. The QC cycle for a cell is indicated by a white circle on the cell status screen (see Figure 4-4, View Cell Status Screen, on page 4-6).

Note - *The maximum time a cell may be disabled while undergoing the QC cycle is 12 minutes.*

Solution: Perform the following procedure:

1. Remove the bottle from the cell that was just loaded.

   The error will disappear.
2. Scan the Bottle ID again and Accession Number (if needed).
3. Reload the bottle into an available cell (one which has its cell indicator light lit).

#910 Invalid Cell Load

Cause: Indicates that a bottle was loaded in a cell that is disabled or non-functional. This error also occurs if a bottle is loaded while an Unload function is active.

Solution: Perform the following procedure:

1. Remove the bottle from the cell that was just loaded. The cell ID will be displayed in the error window on the Instrument.
2. If in the Load function, re-scan the bottle ID and load the bottle in a cell which has its cell indicator light lit. Removing the indicated bottle also causes the Operator Error screen to vanish.

DO NOT CLICK the **Check** button on the Operator Error screen except to intentionally ignore the error and leave the bottle loaded.

Loading another bottle will clear the error and leave the original bottle loaded in the non-functional cell.

#911 Invalid Cell Unload

Cause: Indicates an incorrect bottle was unloaded from a non-indicated cell or that a bottle was unloaded while not in an Unload function.

Solution: Replace the bottle into the cell from which it was just unloaded. The cell ID will be displayed in the error window on the Instrument. The cell will also have a rapidly flashing cell indicator light. Reloading the indicated bottle also causes the Operator Error screen to vanish.

Click the **Check** button ONLY if the unload was intentional.

#912 Invalid Cell Reload

Cause: When reloading a bottle, the bottle was placed in a disabled or non-functional cell.

Solution: Perform the following procedure:

1. Remove the bottle from the non-functional cell whose cell indicator light will be flashing rapidly. The cell ID will also be displayed in the error window on the Instrument.
2. Reload the bottle into a functional cell. Moving the indicated bottle to another cell causes the Operator Error screen to vanish.

DO NOT CLICK the **Check** button on the Operator Error screen except to intentionally ignore the error and leave the bottle loaded in the nonfunctional cell.

Ignoring the error leaves the original bottle in a nonfunctional cell.

#913 Bottle ID Just Entered Matches that of a Currently Loaded Bottle

Note - *The bottle ID just entered is displayed at the top of the Operator Error screen. The cell location of a bottle loaded with the same ID is displayed below the bottle ID.*

Cause: The bottle ID is incorrect for the bottle being loaded or unloaded.

Solution: Rescan the bottle and click the **Check** button after it turns red.

Cause: If the bottle ID is correct for the bottle being loaded or unloaded, the bottle ID for the bottle in the cell location indicated was incorrect.

Solution: Perform the following procedure:

1. Record the cell location displayed in the Error Box.
2. If the error occurred while loading, then do not load the bottle at this time. Set the bottle aside and go to Step 4.
3. If the error occurred while unloading an anonymous bottle, return the bottle to its original cell location.
4. Pull the bottle from the cell recorded in Step 1 and record its bottle ID. (Ignore the Operator Error 911 that appears. DO NOT click the **Check** button.)
5. Return the above bottle to the cell from which it came (the LED will be flashing).
6. Go to the Edit Cell Contents screen and select the cell recorded in Step 2 (see Selecting Bottles Using the Edit Cell Contents Button in Chapter 5). The Edit Bottle Detail screen will display.
7. Enter the correct *bottle ID* (the one recorded in Step 4) in the **Bottle ID** field.
8. Click the **Check** button.
9. If the error occurred while identifying an anonymous bottle, identify the anonymous bottle.

   or

   If the error occurred while loading a bottle (see Step 2), re-load the bottle from Step 2).
10. If the error persists, call bioMérieux.

#921 BARCODE SCAN NOT ALLOWED IN THIS MODE

Cause: Indicates a barcode label was scanned but current screen does not accept barcodes. Frequently occurs if appropriate function is not initiated, such as load or unload bottles.

Solution: No action is required to correct this error. It automatically resolves after 2 seconds.

#923 Invalid Barcode Entry

Cause: The scanned barcode cannot be accepted because it is the wrong length, has the wrong starting character, or has an invalid character.

- Unacceptable bottle ID characters are ', ", \,*.
- Unacceptable Accession Number characters are ‘, “, \, *, @.

Solution: Acknowledge error and rescan bottle. If error persists after rescanning the barcode, attempt to enter the *accession number* or *bottle ID* via the keyboard.

Ensure that barcode is entered into the correct field.

If error persists, use a Generic bottle ID barcode.

#930 Incorrect or Unexpected Barcode Label Scanned while Unloading a Bottle

Cause: A previously identified bottle is unloaded, but the wrong label was scanned while unloading the bottle. The instrument determines that it is not the same barcode currently associated with the bottle and reports this error.

Note - *Two bottle IDs are displayed in a box on the Operator Error screen. At the top is the bottle ID of the bottle just unloaded and scanned. The second bottle ID displayed was assigned to the bottle when it was originally loaded or identified.*

Solution: If an error was made during the scanning of the bottle, rescan the bottle and click the **Check** button after it turns red.

Cause: The correct barcode label is scanned after unloading the bottle; apparently, the incorrect label was scanned when the bottle was originally loaded.

Solution: Perform the following procedure:

1. If the unloaded bottle was scanned correctly, DO NOT click anywhere on the screen.
2. Record the bottle ID and the cell ID, and return the bottle to the cell from which it came.
3. Go to the Select Bottle to Edit screen and use the scroll buttons to enter the cell ID recorded.
4. Click the **Check** button to display this bottle's information on the Edit Bottle Detail screen. Edit the bottle ID to match the bottle ID recorded and click the **Check** button.
5. Return to the Unload function to unload the original bottle.
6. If the error persists, call bioMérieux.

#931 Detection Algorithm has been Changed

Cause: An anonymous or identified bottle is unloaded and its barcode is scanned. The instrument determines that the media type associated with the barcode does not match the algorithm used in analyzing the initial data.

Solution: Perform the following procedure:

1. If the bottle has multiple labels, it may be that the wrong label was scanned. Try rescanning the bottle ID and if correctly entered, click the **Check** button.
2. If no changes are made and the **Check** button is clicked, the bottle will be flagged positive, and Instrument Fault Code 74 or 77 will appear in the cell where the bottle was loaded.
3. Unload the bottle with the fault via the Positive Bottle Unload function.
4. Subculture the bottle and reload the bottle to restart testing (see Instrument Fault Code #74 on page 8-10).

Note - *Unload another bottle or click the* ***Cancel*** *button to ignore the error.*

WARNING – The bottle must be subcultured.

Cause: An anonymous bottle is unloaded with a generic barcode label. The operator uses the **Bottle Type** scroll button to specify the media type. The error is reported while selecting the bottle type.

Solution: Perform the following procedure:

1. Note that the Operator Error screen also has a **Bottle Type** scroll button. If an incorrect media type was entered, correct it now and click the **Check** button.
2. See instructions above if no changes are made and the **Check** button is clicked.

Note - *Unload another bottle or click the* ***Cancel*** *button to ignore the error.*

WARNING – The bottle must be subcultured.

#932 Bottle ID Scanned Matches that of a Previously Unloaded Bottle

Cause: An anonymous bottle is identified with a previously unloaded bottle's ID.

Solution: If the bottle ID was entered incorrectly, enter the correct *bottle ID* and click the **Check** button.

If the bottle ID was entered correctly, perform the following procedure:

1. Re-enter the *bottle ID* and click the **Check** button.

Note - *The bottle readings for the previously unloaded bottle will be lost and the bottle ID, Accession Number, First Loaded Time, Maximum Test Time, and Bottle Type will be assigned to the newly identified bottle.*

2. Reload the bottle, if desired. Instrument Fault Code 78 appears and the bottle is flagged positive (see Instrument Fault Code #78 on page 8-11).

CAUTION – Performing Step 1 and Step 2 result in duplicate bottle ID's that will be seen in Editing Bottle ID to Accession Number relationships and on the reports in the BacT/ALERT® 3D Select and SelectLink configurations.

3. If the bottle is not reloaded (and another bottle is unloaded or the **Cancel** button is clicked), the bottle's anonymous record will be lost.

If the bottle is returned to its cell without identifying the bottle, the bottle will remain anonymous and error code 932 will disappear.

#940 Bottle Detail Not Found

Cause: Occurs only in the Select Bottle to Edit/Graph screen when:

- An empty cell is selected.
- The bottle ID entered is not recognized as belonging to a currently loaded or recently unloaded bottle.

Solution: This Operator Error Code will terminate spontaneously after being briefly displayed. When the Select Bottle to Edit/Graph screen is redisplayed, correct the previous entry or click the **Cancel** button.

Cause: This error may occur while in the Edit Cell Contents screen when a loaded cell is selected, but no bottle record was found.

Solution: Call bioMérieux.

#941 Bottle ID Entered Matches that of a Bottle that is Currently Loaded in a Different Cell

Cause: When editing a bottle ID on the Edit Bottle Detail Screen, the bottle ID entered is the same as the bottle ID of a bottle loaded in a different cell. Click the **Cancel** button to clear the error.

Solution: If the bottle ID was entered incorrectly, enter the correct *bottle ID* now and click the **Check** button.

If the bottle ID is correctly entered, perform the following procedure.

1. Click the **Cancel** button on the Edit Bottle Detail screen.
2. Enter the same *bottle ID* (the one used on the previous screen) and click the **Check** button to view information on this bottle. Note the cell location on the Edit Bottle Detail screen and remove the bottle currently in that cell to record the actual bottle ID. Ignore the Operational Error 911 that appears on the screen when the bottle is unloaded.

   CAUTION – DO NOT click the Check button.
3. Return the bottle to the same cell from which it was removed.
4. Correct the bottle ID and click the **Check** button. It is now possible to edit or identify the original bottle ID.

#942 Bottle Type Change Requires Different Algorithm

Cause: In the Edit Bottle Detail screen, a bottle's media type has been changed to a media type that requires different data analysis.

Solution: If an error was made entering the new media, perform the following procedure:

1. Click the **Cancel** button and return to the Edit Bottle Detail screen to correct the entry.
2. Click the **Check** button on the Edit Bottle Detail screen to save the changes.

If an error was not made, perform the following procedure:

1. Click the **Check** button to override the error. Note the cell ID of the bottle.
2. Click the **Check** button on the Edit Bottle Detail screen to save changes.
3. Go to the View Cell Status screen and check the cell for Instrument Fault Code 74.
4. If the fault is present, follow the procedure provided to correct the problem (see Instrument Fault Code #74 on page 8-10).

943 Identified Bottle Changed to Anonymous

Cause: The **Bottle ID** field has been cleared for an identified bottle in the Edit Bottle Detail screen.

Solution: Click **Cancel** to return to the Edit Bottle Detail Screen. Enter the correct *bottle ID* and click the **Check** button.

944 Manual Unload of Anonymous Bottle

Cause: An attempt was made to manually unload an anonymous bottle from the Edit Bottle Detail screen.

Solution: Click the **Cancel** button to return to the Edit Bottle Detail screen. Enter a *bottle ID* or change the **Load Status** slidebar switch back to the load position (**1**).

945 Bottle ID Entered Matches that of a Previously Unloaded Bottle

Cause: In the Edit Bottle Detail screen, a bottle has been given the bottle ID of a previously unloaded bottle.

Solution: If the bottle ID was entered incorrectly, perform the following procedure:

1. Click the **Cancel** button on the error screen.
2. Enter the correct *bottle ID* on the Edit Bottle Detail screen and click the **Check** button.

If the bottle ID was entered correctly, perform the following procedure:

1. Click the **Check** button on the error screen.

Note - *The bottle readings for the previously unloaded bottle will be lost and the bottle ID, Accession Number, First Loaded Time, Maximum Test Time, and Bottle Type will be assigned to the newly identified bottle.*

2. Click the **Check** button on the Edit Bottle Detail screen. Instrument Fault Code 78 appears and the bottle is flagged positive (see Instrument Fault Code #78 on page 8-11).

960 Duplicate Entries

Cause: Two or more label entry fields on the Label Entry screen contained the same entry when the **Check** button was clicked.

Solution: Change one of the duplicate labels to a unique entry and click the **Check** button.

961 Invalid Blank Field

Cause: One of the label entry fields on the Label Entry screen was blank when the **Check** button was clicked.

Solution: Enter a *label* in the blank field and click the **Check** button.

Bottle Problems

ANONYMOUS BOTTLE INDICATED IN EMPTY CELL

Cause: The cell flag is stuck.

Solution: Verify that the flag is covering the bottom of the cell. If not, try gently clicking on the flag spring to dislodge it.

Cause: Flag is soiled.

Solution: Call bioMérieux.

Cell may need to be recalibrated. Calibrate cell (see Calibrating an Instrument Cell in Chapter 7).

BOTTLE LODGED IN CELL

Cause: Too many labels applied to a bottle.

Solution: Call bioMérieux.

CAUTION – Do not twist the bottle.

Cause: The bottle label was wet when the bottle was loaded and became stuck to the side of the cell.

Solution: Call bioMérieux.

User Output Device Problems

CELL INDICATOR LIGHT(S) NEVER COME ON

Cause: Various.

Solution: Call bioMérieux.

INSTRUMENT ALARM NOT SOUNDING

Cause: Alarm disabled.

Solution: Verify the alarm settings are correct (see Setting the Audible Alarms in Chapter 6). If this does not correct the problem, call bioMérieux.

BARCODE SCANNER DOESN'T BEEP

Cause: Various.

Solution: Call bioMérieux.

Barcode Cannot Be Scanned

Cause: The barcode gun needs cleaning.

Solution: Wipe the face of the gun with a soft cloth and water.

Cause: The connectors are improperly plugged in.

Solution: Perform the following procedure:

1. Power down the Instrument (see Instrument Reboot/ Shutdown in Chapter 7).
2. Make sure the barcode scanner is firmly connected at the back of the Instrument (see Figure 2-3, Instrument Rear View, on page 2-10).
3. Restart the Instrument (see Instrument Reboot/ Shutdown in Chapter 7).
4. Call bioMérieux if the problem is not resolved.

Note - *The keyboard may also be used to enter the barcode manually.*

Cause: Scanner's Operational Parameters are no longer set.

Solution: Scan the applicable Reset Barcode (see Figure 8-4 or Figure 8-5) to reset the Operational Parameters.

Figure 8-4: QuickScan® 6000 Reset Barcode

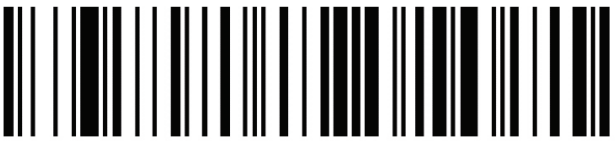

Figure 8-5: Honeywell Reset Barcode

Keyboard Not Responding

Cause: Various.

Solution: Reboot the system (see Instrument Reboot/ Shutdown in Chapter 7).

MONITOR BLANK

Cause: Instrument not receiving power.

Solution: Check the power switch and the power cord connection.

SYSTEM UNRESPONSIVE

Cause: Various.

Solution: Reboot the system (see Instrument Reboot/ Shutdown in Chapter 7). Call bioMérieux if the problem is not resolved.

Note - *The keyboard may be used instead of the mouse to operate the instrument and to activate the load and unload functions (see Using the Keyboard in Place of the Mouse in Chapter 7).*

RED INFORMATIONAL WARNING SCREEN APPEARS

Cause: A red Informational Warning screen indicates that the BIOS clock setting is incorrect.

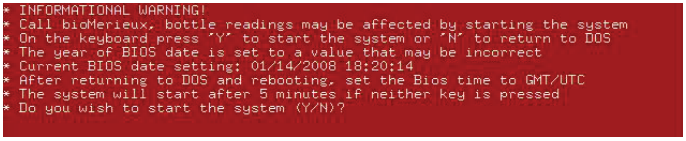
* INFORMATIONAL WARNING!
* Call bioMerieux, bottle readings may be affected by starting the system
* On the keyboard press 'Y' to start the system or 'N' to return to DOS
* The year of BIOS date is set to a value that may be incorrect
* Current BIOS date setting: 01/14/2008 18:20:14
* After returning to DOS and rebooting, set the Bios time to GMT/UTC
* The system will start after 5 minutes if neither key is pressed
* Do you wish to start the system (Y/N)?

Figure 8-6: Informational Warning Screen

Solution 1: If the software was exited and restarted, but the system was not powered off, perform the following procedure:

1. Press **Y** on the keyboard to start the system.
2. Call your local bioMérieux representative immediately to report the incorrect BIOS setting.

Solution 2: If the system was powered off and the Red Information Warning screen (see Figure 8-6) appears when powered on, perform the following procedure:

1. Call your local bioMérieux representative immediately.
2. If a representative is unavailable, press **Y** on the keyboard to start the system.

   All bottles will display Fault Code 72 and/or Fault Code 80 and need to be subcultured.

WARNING – The bottles must be subcultured.

21 CFR PART 11 MODE 9

About This Chapter

This chapter provides you with instructions on how to log in and out of the instrument while in 21 CFR Part 11 mode, as well as instructions for configuring users (ex. adding or deleting a user, or clearing a user password). This chapter also describes the events recorded in the audit trail and how to access the audit trail.

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Log In/Out of System — 21 CFR Part 11 Mode

When installed, the BacT/ALERT® 3D 60 instrument can be configured to operate in 21 CFR Part 11 mode. If 21 CFR Part 11 mode is enabled, you need to enter a user name and password to access all functions available.

While logged out of the instrument in 21 CFR Part 11 mode, the following Main screen is displayed (see Figure 9-1).

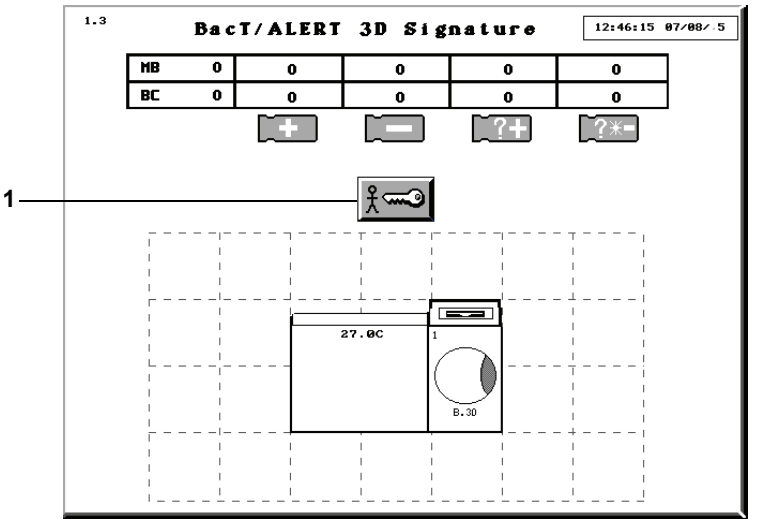

Figure 9-1: Main Screen While Logged Out —21 CFR Part 11 Mode

1 — Login button

When logged out, you will have limited access to the instrument's functions. The following activities can be performed while logged out of the instrument:

- view error status
- view bottle count status
- hear and clear audible alarm
- view screen color changes when a bottle turns positive

Logging In for the First Time

When you log in to the instrument for the first time, the default password is *blank* (see Adding a User on page 9-13).

To log in to the instrument for the first time:

1) From the Main screen while logged out (see Figure 9-1), click the **Login** button ( ).

The User Login screen appears.

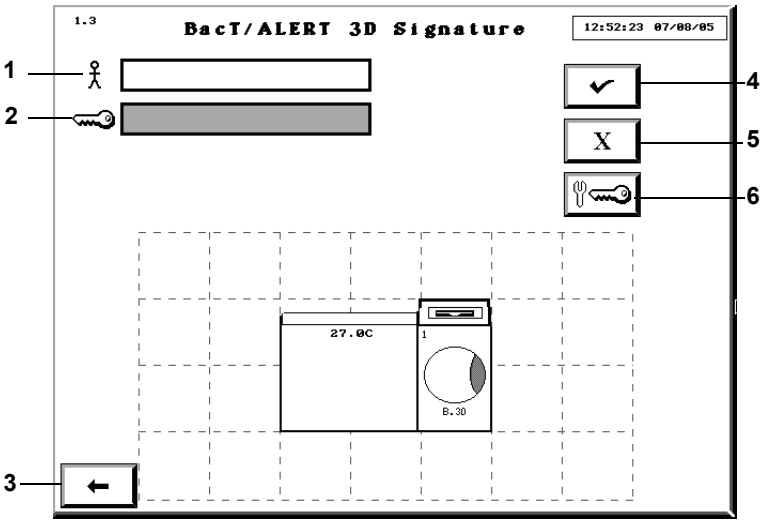

Figure 9-2: User Login Screen

1 — User Name Field
2 — Password Field
3 — Previous Screen Button
4 — Check Button
5 — Cancel Button
6 — Change Password Button

2) Click in the **User Name** field (field turns white) and enter your *user name*.

3) From the User Login screen (see Figure 9-2, User Login Screen), click the **Change Password** button ( ).

The **New Password** and **Confirm Password** fields appear on the **User Login** Screen (see Figure 9-3).

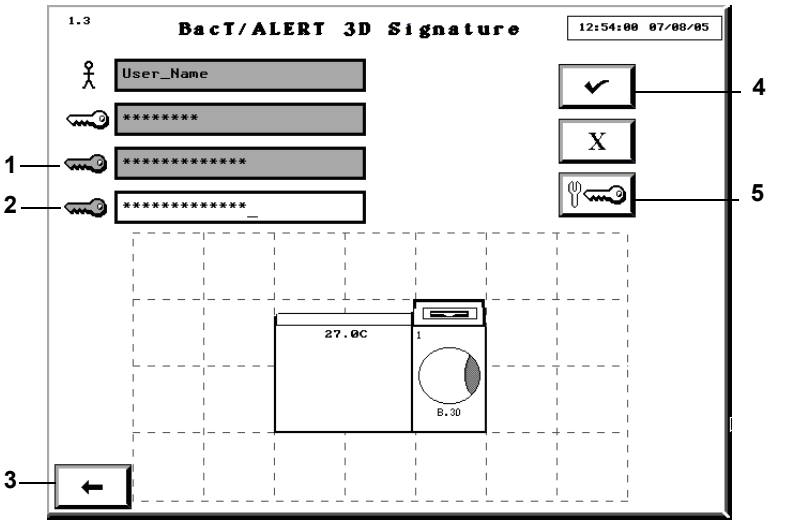

Figure 9-3: User Login Screen with Change Password Fields

1 — New Password Field

2 — Confirm Password Field

3 — Previous Screen Button

4 — Check Button

5 — Change Password Button

4) Enter your new *password* in the **New Password** field (password length must be 6 to 24 characters).

5) Re-enter your new *password* in the **Confirm Password** field.

6) Click either the **Check** button or the **Enter** key to change your password.

The Main screen appears.

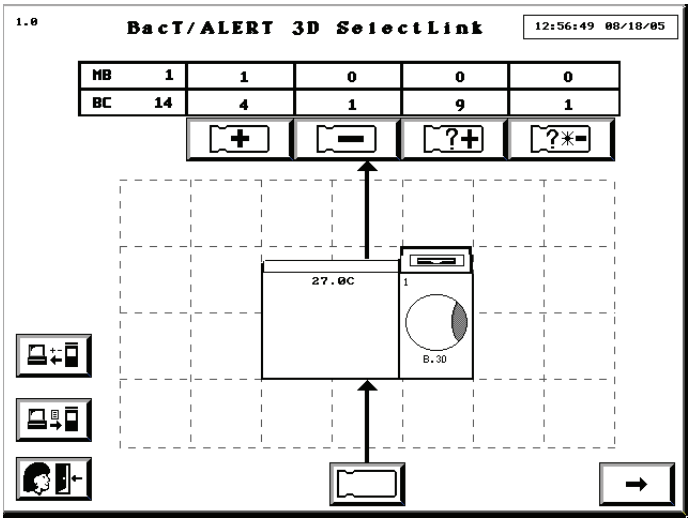

Figure 9-4: Main Screen While Logged In — 21 CFR Part 11 Mode

Note: *The **Previous Screen** button returns to the User Login screen (see Figure 9-5, User Login Screen, on page 9-6) without logging in.*

Logging In

When the instrument is configured for 21 CFR Part 11 mode, you will need to log in to the instrument to have full access of all functions.

1) From the Main screen while logged out (see Figure 9-1), click the **Login** button ( ).

The User Login screen appears.

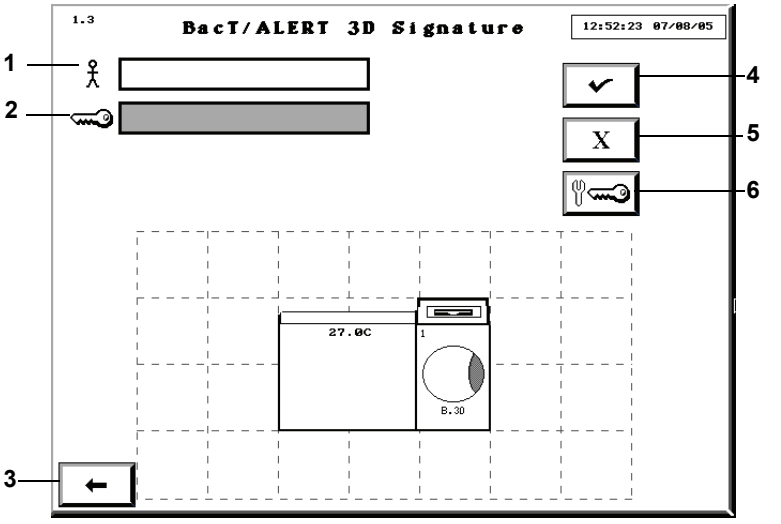

Figure 9-5: User Login Screen

1 — User Name Field
2 — Password Field
3 — Previous Screen Button
4 — Check Button
5 — Cancel Button
6 — Change Password Button

2) Click in the **User Name** field (field turns white) and enter your *user name*.

3) Press the **Tab** key on the keyboard to advance to the **Password** field (or click in the **Password** field).

The **Password** field turns white.

4) Enter your *password* in the **Password** field (password length must be 6 to 24 characters).

5) Click the **Check** button or the **Enter** key to log in to the instrument.

The Main screen appears (see Figure 9-4, Main Screen While Logged In — 21 CFR Part 11 Mode, on page 9-5).

Note: *See Configuring Users — 21 CFR Part 11 Mode on page 9-12 for detailed information on how to add and delete users, and clear user passwords.*

Inactivity Timeout

While you are logged in, an inactivity timeout will occur (within a period of time configured by your bioMérieux Service Representative) if you do not perform one of the following actions:

- press a screen or keyboard button
- scan a barcode
- load or unload a bottle

If an inactivity timeout occurs, the instrument display reverts back to the Login screen (see Figure 9-1, Main Screen While Logged Out —21 CFR Part 11 Mode, on page 9-2). Any pending function is cancelled as if the **Cancel** button on each successive screen was clicked.

Note: *If a timeout occurs, it is possible that partially entered information will be lost.*

Note: *The inactivity timeout feature is disabled while a red operator error is displayed.*

Login Errors

An alert displays on the User Login screen if you enter an unknown user name or an incorrect password and click the **Enter**, **Check** or **Change Password** button (see Figure 9-6).

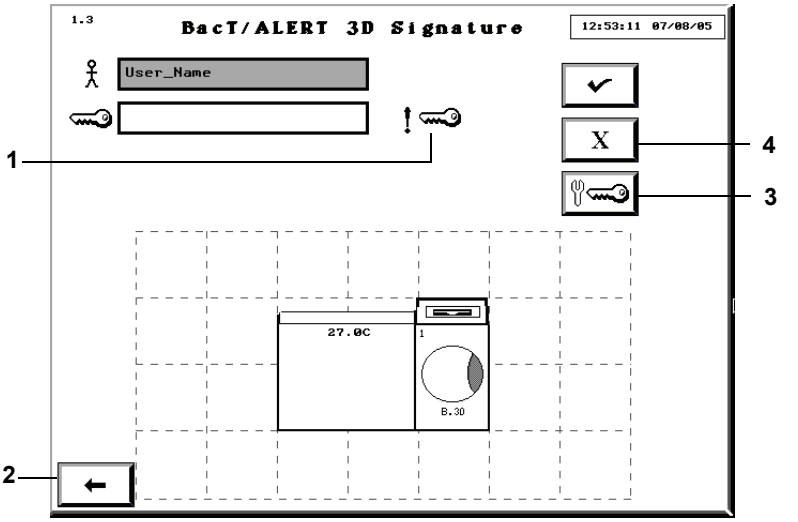

Figure 9-6: User Login Screen with Wrong Password Alert

1 — Wrong Password Alert
2 — Previous Screen Button
3 — Change Password Button
4 — Cancel Button

Note: *A Wrong User Alert (* *) appears to the right of the* ***User Name*** *field.*

To clear the alert:

1) Click the **Cancel** button to clear the alert and all of the fields.

2) Re-enter your *user name* or *password* (see Logging In on page 9-6).

or

Click the **Previous Screen** button to return to the User Login screen without logging in (see Figure 9-5, User Login Screen, on page 9-6).

Change Password

Once you have entered a valid user name and password, you can change your password.

1) From the User Login screen (see Figure 9-5, User Login Screen), click the **Change Password** button ( ).

The **New Password** and **Confirm Password** fields appear on the **User Login** Screen (see Figure 9-7).

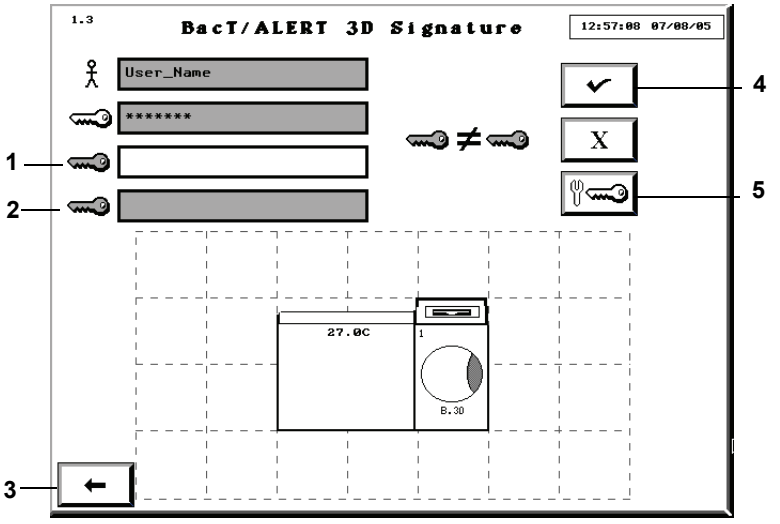

Figure 9-7: User Login Screen with Change Password Fields

1 — New Password Field
2 — Confirm Password Field
3 — Previous Screen Button
4 — Check Button
5 — Change Password Button

2) Enter your new *password* in the **New Password** field.

3) Re-enter your new *password* in the **Confirm Password** field.

4) Click either the **Check** button or the **Enter** key to change your password.

Note: *The **Previous Screen** button returns to the User Login screen (see Figure 9-5, User Login Screen, on page 9-6) without logging in.*

Change Password Errors

If you enter an incorrect new password, a change password error appears on the User Login screen (see Figure 9-8). If you enter a password with less than 6 characters, a wrong password alert appears on the User Login screen (see Figure 9-9).

Note: *If more than 24 characters are entered, the additional characters are ignored and no error is displayed.*

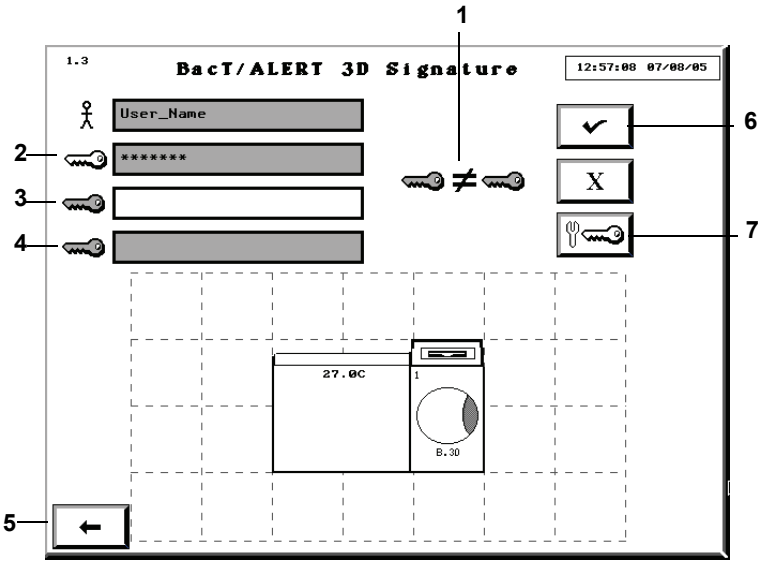

Figure 9-8: User Login Screen with Change Password Error

1 — Change Password Error
2 — Password Field
3 — New Password Field
4 — Confirm Password Field
5 — Previous Screen Button
6 — Check Button
7 — Change Password Button

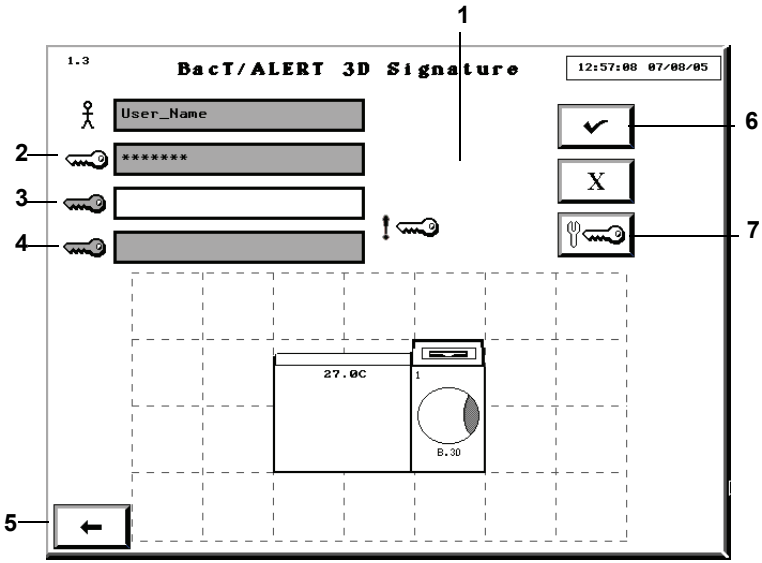

Figure 9-9: User Login Screen with Wrong Password Alert

1 — Wrong Password Alert
2 — Password Field
3 — New Password Field
4 — Confirm Password Field
5 — Previous Screen Button
6 — Check Button
7 — Change Password Button

To clear the password error:

1) Click in the **Password** field.

The **New Password** and **Confirm Password** fields will clear.

2) Enter your new *password* in the **New Password** field.

3) Re-enter your new *password* in the **Confirm Password** field.

4) Click the **Check** button or the **Enter** key to change your password.

Note: *The **Previous Screen** button returns to the User Login screen (see Figure 9-5, User Login Screen, on page 9-6) without logging in.*

Logging Out

1) From the Main screen (see Figure 9-4, Main Screen While Logged In — 21 CFR Part 11 Mode, on page 9-5), click the **Logout** button ( ) to log out of the instrument.

   The Main screen (while logged out) appears (see Figure 9-1, Main Screen While Logged Out —21 CFR Part 11 Mode, on page 9-2).

Note: *If you do not log out, the system will automatically time out when it reaches the inactivity timeout period (see Inactivity Timeout on page 9-7).*

Configuring Users — 21 CFR Part 11 Mode

The User Configuration screen allows you to manage user accounts for up to 100 users. You can add users, delete users, and clear user passwords.

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) From the Setup screen (see Figure 4-9, Setup Screen), click the **Configure Users** button ( ).

The User Configuration screen appears.

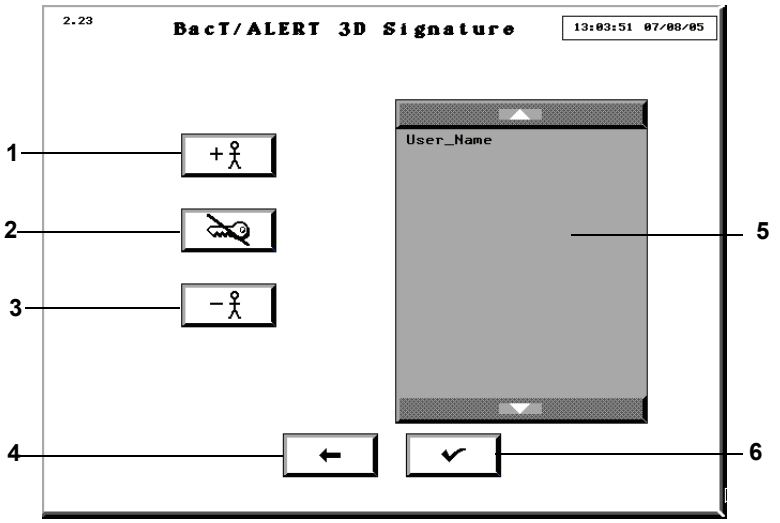

Figure 9-10: User Configuration Screen

1 — Add User Button
2 — Clear Password Button
3 — Delete User Button
4 — Previous Screen Button
5 — User List
6 — Check Button

Note: *The **Configure Users** button is only active when the instrument is configured for 21 CFR Part 11 mode.*

Adding a User

To add a user to the User List:

1) From the User Configuration screen (see Figure 9-10, User Configuration Screen), click the **Add User** button ( ).

The Add User screen appears.

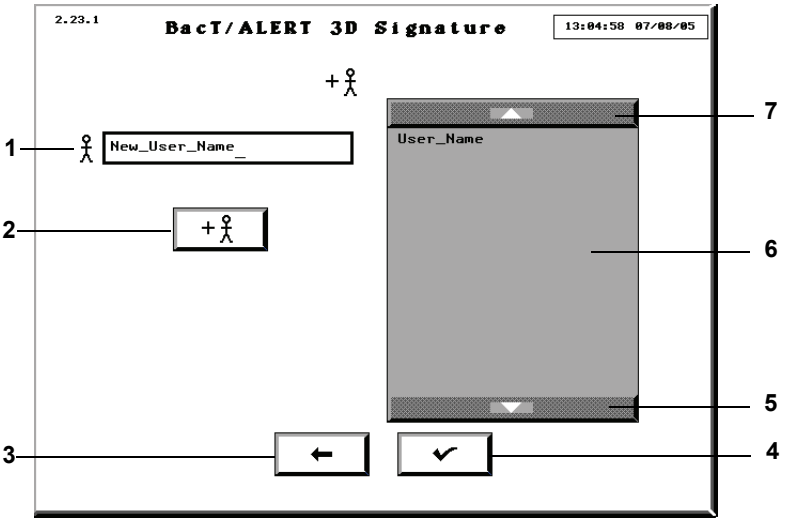

Figure 9-11: Add User Screen

1 — User Name Field
2 — Add User Button
3 — Previous Screen Button
4 — Check Button
5 — Scroll Down Button
6 — User List
7 — Scroll Up Button

Note: *Multiple users can be added without leaving this screen.*

2) Click in the **User Name** field (field turns white) and enter the *user name*.

The minimum user name length is 1 character and the maximum is 24 characters.

Note: *Do not use the asterisk (*) when adding a user name.*

3) Click the **Add User** button or the **Enter** key.

The new user is added to the User List.

4) Click the **Check** or **Previous Screen** button to return to the User Configuration screen.

Note: *When you log in to the instrument for the first time, the default password is blank. See Logging In for the First Time on page 9-2, to set your password.*

Deleting a User

To delete a user from the User List:

1) From the User Configuration screen (see Figure 9-10, User Configuration Screen, on page 9-13), click the **Delete User** button ( ).

The Delete User screen appears.

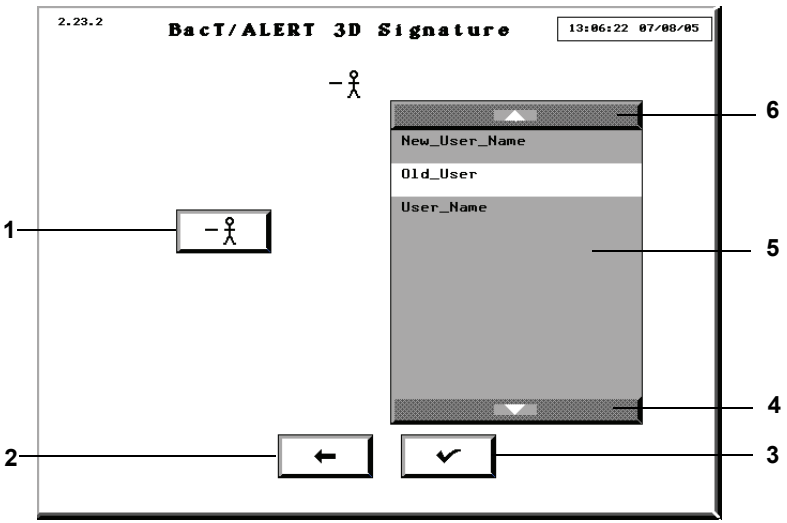

Figure 9-12: Delete User Screen

1 — Delete User Button
2 — Previous Screen Button
3 — Check Button
4 — Scroll Down Button
5 — User List
6 — Scroll Up Button

2) Click the **Scroll Up** or **Scroll Down** button to locate the user name to be deleted.

3) Click the user name to select.

4) Click the **Delete User** button to delete the selected user from the User List.

5) Click the **Check** or **Previous Screen** button to return to the User Configuration screen.

Deleting More Than One User

To delete more than one user at a time:

1) From the Delete User screen (see Figure 9-12), click on the user names to select.

Note: *If you select the wrong user name, click on the user name again to deselect.*

2) Click the **Delete User** button to delete the selected users from the User List.

3) Click the **Check** or **Previous Screen** button to return to the User Configuration screen.

Clearing a User Password

In the event you may need to clear a user's password (ex. a user forgets their password), perform the following procedure.

1) From the User Configuration screen (see Figure 9-10, User Configuration Screen, on page 9-13), click the **Clear Password** button ( ).

The Clear Password screen appears.

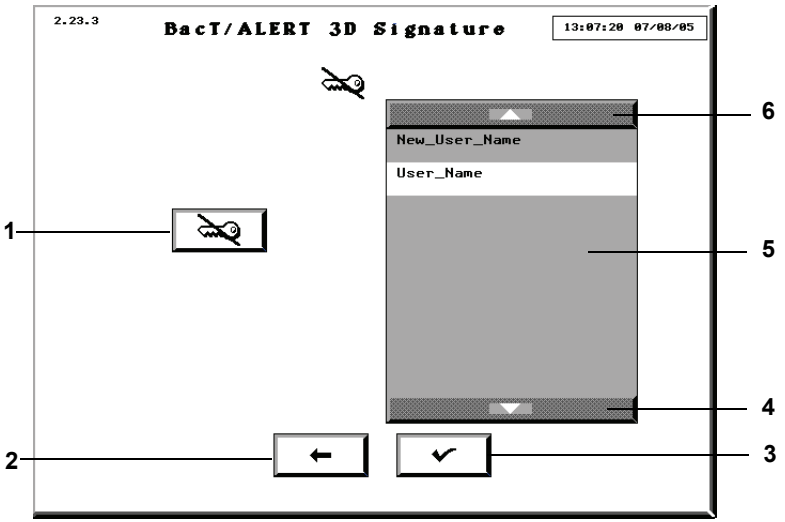

Figure 9-13: Clear Password Screen

1 — Clear Password Button
2 — Previous Screen Button
3 — Check Button
4 — Scroll Down Button
5 — User List
6 — Scroll Up Button

2) Click the **Scroll Up** or **Scroll Down** button to locate the user name.

3) Click the user name to select.

4) Click the **Clear Password** button to clear the password for the selected user.

5) Click the **Check** or **Previous Screen** button to return to the User Configuration screen.

Note: *When you clear a user password, the password is reset to the blank setting. The user will then have to recreate a password (see Logging In for the First Time on page 9-2).*

Clearing More Than One User Password

To clear more than one user password at a time:

1) From the Clear Password screen (see Figure 9-13), click on the user names to select.

Note: *If you select the wrong user name, click on the user name again to deselect.*

2) Click the **Clear Password** button to delete the passwords for the selected users from the User List.

3) Click the **Check** or **Previous Screen** button to return to the User Configuration screen.

Audit Trail

One of the features of 21 CFR Part 11 mode is an audit trail that records activities and other related information (ex. bottle events). Each audit trail entry consists of an event, the time and date the event occurred. See Table 9-1 for a list of events recorded in the audit trail.

Table 9-1: Audit Trail Events

Event	Event Parameters
User Log in	Time, Date, User ID
User Log out	Time, Date, User ID
Anonymous Bottle First Loaded	Time, Date, User ID, Cell Location, Max Test Time, Sequence Number
Identified Bottle First Loaded	Time, Date, User ID, Cell Location, Bottle Type, Max Test Time, Bottle ID, Accession Number, Sequence Number
Bottle Identified	Time, Date, User ID, Cell Location, Bottle Type, Max Test Time, Bottle ID, Accession Number, Sequence Number
Bottle Moved	Time, Date, User ID, Original Cell, Destination Cell, Sequence Number
Bottle Unloaded	Time, Date, User ID, Cell Location, Sequence Number

Table 9-1: Audit Trail Events (Continued)

Event	Event Parameters
Bottle Record Changed	Time, Date, User ID or LIS, Cell Location, Action (Bottle Type Changed, Loaded Status Changed, Max Test Time Per Bottle Changed, Test Result Manually Changed, Bottle ID Changed, Accession Number Changed), Sequence Number, Bottle Type, Loaded Status, Max Test Time, Test Result, How Determined, Bottle ID, Accession Number ***Note -*** *The Bottle Type, Loaded Status, Max Test Time, Test Result, How Determined and Accession Number are recorded in the Audit Trail when they change.*
Temperature Calibration	Time, Date, User ID, Chamber ID, New Temperature Setpoint
Cell Calibration	Time, Date, User ID, Cell Location
Display Time Changed	Time, Date, User ID, Amount of Change relative to UTC (Universal Coordinated Time)
Firmware Updated	Time, Date, Device, Firmware Revision ***Note -*** *User ID is not recorded.*
Rack, or Cell Enabled or Disabled	Time, Date, User ID, Location, Action (enable or disable), Device ***Note -*** *This event is recorded only from the Enable/Disable Rack or Cell screen (screen 2.2).*
Maximum Test Time for Bottle Type Changed	Time, Date, User ID, Bottle Type, Max Test Time
Positive Alarm Setting Changed	Time, Date, User ID, Action (enable or disable)
Instrument Alarm Setting Changed	Time, Date, User ID, Action (enable or disable)
Operator Error Alarm Setting Changed	Time, Date, User ID, Action (enable or disable)
System Password Changed	Time, Date, User ID
21 CFR Part 11 Mode Changed	Time, Date, User ID, Action (enable or disable) ***Note -*** *User ID is recorded only for disable.*

Table 9-1: Audit Trail Events (Continued)

Event	Event Parameters
User Account Changed	Time, Date, User ID, Action (user added, user deleted, password changed or cleared)
Patient Name Changed	Time, Date, User ID, Hospital ID, First Name, Last Name
Hospital ID Changed	Time Date, User ID, Accession Number, Hospital ID
Cell Gap Detection Faults Cleared	Time, Date, User ID, Number of bottles cleared

Note: *Some recorded events may occur while you are logged out and will not have an associated User ID (ex., upgrading firmware). In these cases, the user is listed as "Unknown".*

Note: *The audit trail is available on all BacT/ALERT® 3D 60 software configurations, regardless of 21 CFR Part 11 status.*

Accessing the Audit Trail

The audit trail is available in English only and is not editable. The audit trail is available as one of the Software Test screens.

To access the audit trail:

1) Access the Setup screen and enter a valid password (see Accessing the Setup Screen Function Buttons in Chapter 4).

2) From the Setup screen, press **Ctrl + D** on the keyboard.

The Software Test screen appears.

3) Press the **7** key on the keyboard.

The Audit trail appears in the Software Test screen window.

MYCOBACTERIAL TESTING 10

About This Chapter

This chapter provides you with a complete description of the of the BacT/ALERT® 3D 60 instrument when it is configured for Mycobacterial (MB) functions.

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System Description

Intended Use

The Mycobacterial (MB) configuration of the BacT/ALERT® 3D 60 instrument is designed to grow and detect mycobacteria from patient samples.

Overview

The BacT/ALERT® 3D 60 system uses no radioactive reagents, is non-invasive, and offers walk-away automation for mycobacteria detection. No handling of the bottle inoculated with specimen is required after it is placed in the BacT/ALERT® 3D 60 instrument. Positives are signaled immediately upon detection. After a specified time, which can be determined by the operator, negatives are signaled if no growth has been detected.

The BacT/ALERT® 3D 60 instrument can be converted by a service engineer to perform either MB or non-MB functions. One important difference between the configurations is that MB configurations do not agitate the bottles during incubation. It is important to open and close the door gently to minimize avoidable agitation when adding or removing bottles.

The disposable mycobacteria bottles (MB and MP) contain bioMérieux's patented colorimetric sensor which is continuously monitored for positive sample detection. Unloading or manipulating the bottles when not indicated by the system may interfere with critical bottle readings. In addition, the bottles contain broth and atmosphere which promote the recovery of a wide variety of *Mycobacterium* species without venting. MB/BacT® Antimicrobial Supplement and Reconstitution Fluid inhibit the growth of contaminating organisms and enhance the recovery of mycobacteria.

In the following pages, the elements of the MB configuration of the BacT/ALERT® 3D 60 will be described with special emphasis on how they differ from the non-MB configuration described in the rest of this manual. While the function and use of MB configuration are similar to those of non-MB configuration, there are important differences.

WARNING

Laboratory procedures involving mycobacteria require special equipment and techniques to minimize biohazards. Specimen preparation and positive sample handling must be done in a biological safety cabinet.

BacT/ALERT® 3D 60 Instrument

The instrument incubates and continuously monitors the status of each mycobacterial culture bottle. The instrument consists of three racks each with a capacity of 20 bottles. The instrument must be either MB or non-MB.

MB Instrument may be provided directly by bioMérieux or may be converted from a non-MB configuration in the field.

An **MB** is displayed on the **Instrument** icon of the Main Screen (see Figure 10-1).

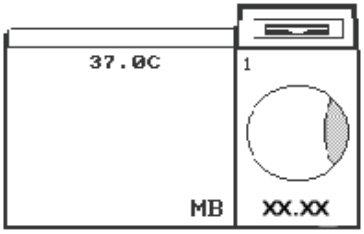


Figure 10-1: Instrument Icon for MB-Configured System

Circulation Fan

The circulation fan, normally running to distribute air within the BacT/ALERT® 3D 60 instrument, is turned off whenever the door is opened.

Note: *The BacT/ALERT® 3D 60 software must also be configured to activate the MB processing (see MB Configuration on page 10-5).*

Installation Procedures and Special Requirements

If it is necessary to move or store the BacT/ALERT® 3D 60 System, contact your local bioMérieux Representative for assistance.

The BacT/ALERT® 3D 60 has been designed to minimize risks associated with Mycobacterial testing. However, to further reduce the risks of accidental exposure to infectious agents, additional precautions should be taken. It is strongly recommended that the instrument be placed in a laboratory used for the routine culture of *M. tuberculosis*. For activities involving the propagation and manipulation of *M. tuberculosis* or *Mycobacterium* species grown in culture, BioSafety Level 3 Practice, Containment Equipment, and Facilities are required as recommended by CDC and NIH guidelines.

At a minimum, the instrument should be placed in a contained environment with controlled access which has a tuberculosis exposure control plan.

The locations should have surfaces which can be easily decontaminated using an appropriate topical disinfectant. The instrument must not be placed in an open corridor or hallway that is accessible to the general public or the patient population.

BacT/ALERT® 3D 60 Software

Barcodes

- Mycobacteria process bottle (MP) barcodes are encoded with the bottle type and have an SM (plastic) prefix.
- Mycobacteria blood bottle (MB) barcodes are encoded with the bottle type and have an !B (glass) prefix.

WARNING

Do not use Generic barcodes to load BacT/ALERT® MB Bottles.

Set Maximum Test Time

The system default maximum test time is 42 days for Mycobacteria bottles. Test times may be changed manually through the Set Maximum Test Time screen (see Setting the Maximum Test Time in Chapter 6).

Positive Detection Algorithm

A special detection algorithm is used to detect growth of *Mycobacterium* species. This algorithm is designed to detect growth at the earliest possible time.

Bottle Status

The Main Screen on the monitor displays the status of positive or negative Mycobacteria bottles separately from the status of other bottle types.

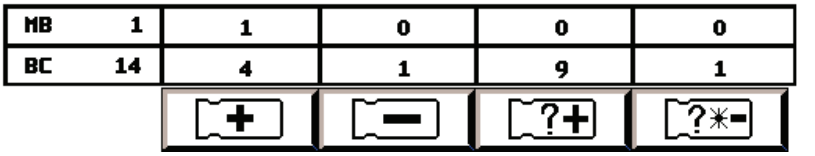


Figure 10-2: Bottle Count Table and Unload Buttons

Located just above the **Instrument** icon on the Main screen are the **Unload** buttons. Above each **Unload** button is a rectangular box containing the number of bottles currently matching the unload criteria for that button.

The Bottle Count Table contains two rows. The top row displays the bottle count for Mycobacteria culture bottles and is labeled **MB**. The bottom row displays the bottle counts for non-mycobacterial culture bottles and is labeled **BC**.

The leftmost box in each bottle count row contains the culture type label (ex. BC, MB) and is not associated with an **Unload** button. The number displayed within this box represents the total number of bottles (of any status) currently loaded into the system.

The second leftmost box shows the total number of identified bottles with a positive test status. It appears above the **Positive Bottle** icon.

The box third from the left shows the total number of identified and anonymous bottles with a negative test status. It appears above the **Negative Bottle** icon.

The box second from the right shows the total number of anonymous bottles with a positive test status, and is associated with the corresponding icon.

The total number of anonymous bottles with a negative-to-date or negative test status appears rightmost, and is associated with the corresponding icon.

System Startup

General Information

The installation of the BacT/ALERT® 3D 60 instrument is described in Chapter 3, System Installation.

MB Configuration

The BacT/ALERT® 3D 60 agitation mechanism can be disengaged at the factory or by a service engineer on site, after which the three racks remain immobile. The BacT/ALERT® 3D 60 Instrument is also configured by bioMérieux personnel to activate the MB status.

Limitations of the Test

Refer to the package insert enclosed with the Mycobacteria Process Bottles (MP) for additional information.

Service and Maintenance

Preventive maintenance and troubleshooting are performed as described in Chapter 7, System Maintenance.

Additional procedures pertinent to Mycobacteria are referenced in this chapter (see Safety Features on page 10-7).

Theory of Operation

The MB/BacT® Mycobacterial Detection System utilizes a colorimetric sensor and reflectance detector to determine the level of carbon dioxide within the bottle. If microorganisms grow in the bottle, carbon dioxide is produced which will change the color of the sensor on the bottom of the bottle. The instrument monitors this color while incubating the sample and determines if growth has occurred.

The Mycobacteria Process Bottles (MP) contain a media which will, in combination with the MB/BacT® Reconstitution Fluid, promote the growth of mycobacteria. If a non-sterile sample is tested, the Reconstitution Fluid should be combined with the MB/BacT® Antibiotic Supplement, which is then added to the Process Bottle in accordance with the instructions in the package insert. The addition of these antibiotics inhibits the growth of contaminating, non-mycobacterial microorganisms while permitting the growth, detection, and recovery of mycobacteria.

Principle of Detection

Mycobacteria behave like most other aerobic bacteria with respect to carbohydrate metabolism, energy production, and the biosynthesis of low weight metabolites. They are able to assimilate a large range of carbohydrates, lipids, and proteins. How mycobacteria assimilate and organize these substrates is shown diagrammatically in Figure 10-3 below.

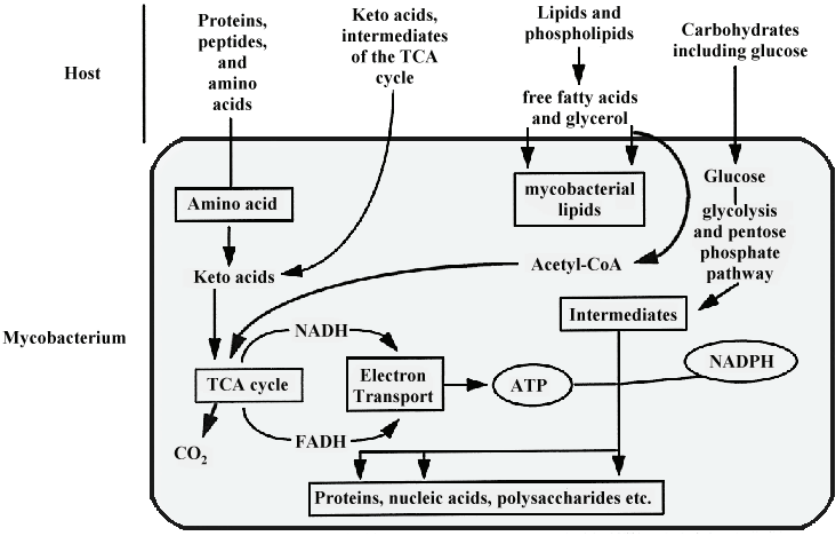


Figure 10-3: Metabolic Pathway for Mycobacterial CO_2

Glycerol was selected as the primary metabolic source in the MP Bottle because of its unique metabolic pathway and its ability to maximize the amount of CO_2 generated by mycobacteria. Once ingested, glycerol is converted to Acetyl-CoA and oxidized through the Krebs or Tricarboxcilic Acid Cycle (TCA). CO_2 and reduced electron carriers are the major metabolic byproducts of this oxidation.

A solid-state sensor at the base of each MP Bottle detects CO_2 as an indicator of microbial growth. As the concentration of CO_2 increases, the sensor undergoes a color change from green to yellow.

Safety Features

The design of the BacT/ALERT® 3D 60 provides several safety measures to help mitigate hazards associated with mycobacteria and other organisms in the interest of operator and laboratory safety. They are summarized as follows.

- All glass bioMérieux BacT/ALERT® media bottles are manufactured with a polymeric safety sleeve to help limit the effects of damage to a bottle. Plastic bottles are made from a break-resistant material.
- Each bottle cell within the BacT/ALERT® 3D 60 Instrument is sealed to help contain and minimize effects of liquid spillage.
- The circulating fans within the Instrument turn off whenever the door is open to minimize airflow and the potential for aerosols.

- To reduce the chance of binding a heavily overlabeled bottle in a cell, Instrument cells are gently tapered and fabricated from a compliant polymer.

WARNING

Pathogenic Microorganisms including Hepatitis B virus and Human Immunodeficiency Virus (HIV) may be present in specimens. *Universal Precautions* and Local Laboratory guidelines should be followed in handling all items contaminated with blood or body fluids. If an inoculated tube is found to be leaking or is accidentally broken during collection or transport, use the established procedures in your facility for dealing with Mycobacterial spills. As a minimum, *Universal Precautions* should be employed. Tubes should be discarded in an appropriate manner.

General Precautions

The following precautions should be observed during Maintenance and Repair, even in situations where a spill is neither observed nor suspected. At a minimum, disposable gloves, eye protection, and a laboratory coat should be worn. Any parts removed or tools used should be decontaminated using a 10% bleach solution or other EPA registered tuberculocidal disinfectant before removal from the laboratory. Anything which cannot be disinfected should be sealed in a plastic bag, labeled as biohazardous, and handled accordingly. In addition, the institution's safety precautions should always be observed. Refer to *Biosafety in Microbiological and Biomedical Laboratories*. HHS Publication No. CDC 93-8395. US Dept of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, ed 3, 1993, pp 93-96.

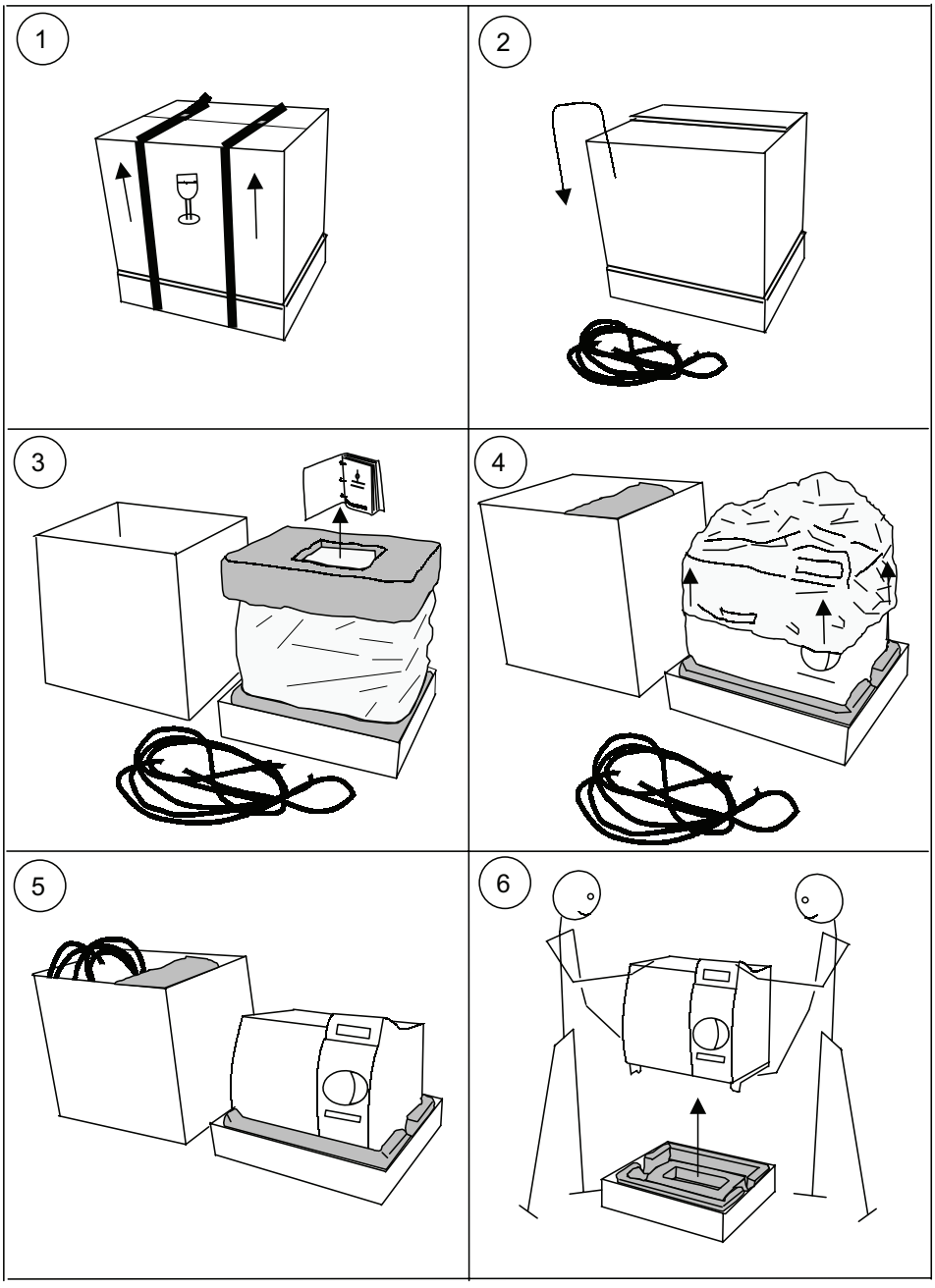
Spill Cleanup

For specific spill cleanup procedures, see Safety Precautions and Procedures in Chapter 7. (See also Spill Cleanup in Chapter 7.)

Disinfection Procedure for Spills Within/Onto the Instrument

If a spill is detected, only persons wearing protective clothing including gloves, and a HEPA filter respirator should remain in the room. Any test specimen spilled in an instrument should be removed immediately using the disinfection procedures (see Disinfection Procedure for Spills Onto the Instrument in Chapter 7).

BacT/ALERT® 3D 60 Unpacking Instructions



BacT/ALERT® 3D 60 Part Checklist

SITE NAME _____ **SERIAL #** _____

CITY, STATE _____ **SERVICE CALL #**_____

The following checklist can be used when verifying and inspecting kit contents (see Verifying Contents in Chapter 3).

Contents

- ☐ BacT/ALERT® 3D 60 Instrument
- ☐ BacT/ALERT® 3D 60 User Manual Multi-language CD
- ☐ 2 ea. 5 amp fuse
- ☐ 1 ea. 6.3 amp fuse
- ☐ 1 ea. blank USB Flash Drive
- ☐ Decontamination Procedure
- ☐ Decontamination Certificate
- ☐ Anonymous BTL Labeling Set – WARNING –
- ☐ Rack - Bottle Carrier BTA
- ☐ Mouse and Mouse Pad
- ☐ Barcode Scanner and Manual
- ☐ Scanner Stand
- ☐ Keyboard
- ☐ Power Cord
- ☐ Printer
- ☐ Parallel Printer cable
- ☐ 1/4" X20X5" bolt
- ☐ 1/4" flat washer
- ☐ UPS
- ☐ UPS Serial Cable
- ☐ CRT Monitor

  or
- ☐ Flat Panel Monitor
- ☐ Calibration Standards Kit

Optional Equipment

- ☐ Speaker Set -- For 110V BacT 3D 60

  or
- ☐ Speaker Set -- For 220V BacT 3D 60
- ☐ Fax Modem – Domestic (Optional)- 120V

  or
- ☐ Fax Modem – International (Optional)
- ☐ Serial Modem Cable (Optional)
- ☐ UPS to Printer Power AC Adaptor
- ☐ UPS to Printer AC Power Cable

Recommended Tools

- ☐ Small flat (plane blade) screwdriver
- ☐ Phillips screwdriver

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BacT/ALERT® 3D 60 Installation Checklist

SITE NAME _____ **SERIAL #** _____

CITY, STATE _____ **SERVICE CALL #**_____

Preparation	Pass	Initials
Site Requirements are met (see page 3-2)	____	_____
Unpack and Verify Contents (see page 3-2)	____	_____
Installation		
AC Power Configuration (see page 3-3)	____	_____
Instrument Placement (see page 3-6)	____	_____
Restraint Installation, if required (see page 3-12)	____	_____
Instrument Connections made (see page 3-7)	____	_____
Instrument powered up (see page 3-9)	____	_____
Configure Instrument (see page 3-10)	____	_____
Temperature Calibration (see page 3-10)	____	_____
Functional Testing		
Modem Function Validation (see page 3-10)	____	_____
Barcode Reader Validation (see page 3-11)	____	_____
UPS Function Validation (see page 3-12)	____	_____
Record Software Revision and Annotate Logbooks	____	_____

The following table shows items that may be connected to the instrument as "shipped" or "optionally installed" parts:

UPS (Domestic or International)	_____	External Speaker Set (Domestic or International)	_____
Monitor (Flat Panel or CRT)	_____	Keyboard (Must be installed with the instrument)	_____
Printer	_____	Barcode Scanner	_____
Modem AC Adapter (Must be installed with modem)	_____	Mouse (Must be installed with the instrument)	_____
Modem (Domestic or International)	_____		

Comments:

_____

_____

_____

_____

_____

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INTERNATIONAL CHARACTER ENTRY D

About This Chapter

This chapter explains how to enter international characters on the BacT/ALERT® 3D 60 instrument.

Chapter Contents

International Character Entry • D-2

Entering International Characters • D-3

International Character Entry

You can enter International characters on the BacT/ALERT® 3D 60. Since the keyboard does not contain the International characters, enter a base character then use the **Page Up** or **Page Down** keys to toggle to the variant character desired.

Each block in the table below lists a base character on the left and the variants that can be accessed from that base character on the right.

Table D-1: International Character Table

Uppercase		Lowercase	
Base Char	**Variant**	**Base Char**	**Variant**
A	À	a	à
	Á		á
	Â		â
	Ã		ã
	Ä		ä
	Å		å
	Æ		æ
			ª
E	È	e	è
	É		é
	Ê		ê
	Ë		ë
I	Ì	i	ì
	Í		í
	Î		î
	Ï		ï

Table D-1: International Character Table (Continued)

Uppercase		Lowercase	
Base Char	**Variant**	**Base Char**	**Variant**
O	Ò	o	ò
	Ó		ó
	Ô		ô
	Õ		õ
	Ö		ö
	Ø		°
	Ù		ø
	Ú		ù
	Û		ú
	Ü		û
	Ý		ü
	Ñ		ý
	Ç		ÿ
	ß		ñ
	µ		ç
	Þ		-
	Þ		-

International characters can be used in any of the following text fields on the system:

- **Accession Number** field
- **Hospital ID** field
- **Patient First Name** field
- **Patient Last Name** field
- **Report Label** fields
- **Report Title** field

Entering International Characters

1) Enter a *base character* from the table. See Manually Entering Text into a Data Entry Field (Keyboard) in Chapter 4.

2) Use the **Page Up** or **Page Down** key to scroll through the characters in the block from the table.

Example: To enter an **Å**, perform one of the following:

- Press **Shift** + **A** then press **Page Up** six times.

or

- Press **Shift** + **E**, then press **Page Down** twice.

Note: *The entire International Character table can be scrolled through after entering one base character. After scrolling through an entire block from the table, the system scrolls to the base character in the next block. For example, if **n** is entered and **Page Up** is pressed twice, then **c** will display.*

BOTTLE QUALITY CONTROL E

About This Chapter

This chapter provides you with a description of the BacT/ALERT® 3D culture bottle along with a quality control procedure.

Chapter Contents

BacT/ALERT® Culture Bottles • E-2

Introduction • E-2

Quality Control of Growth Performance • E-4

BacT/ALERT® Culture Bottles

Introduction

Disposable culture bottles to which samples are added for testing. Each bottle contains a sensor that detects carbon dioxide (CO_2) as an indicator of microbial growth.

BacT/ALERT® culture bottles are ready for use. An expiration date is printed on each bottle label. Do not use the media beyond the last day of the month indicated. If the bottles are refrigerated, precipitates may form that will disappear when the bottles are warmed to room temperature. Store protected from light at room temperature (15–30°C). Bottles must be at room temperature before use.

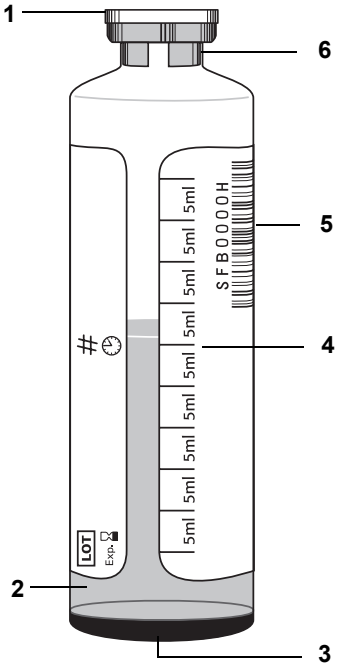

Figure E-1: Typical BacT/ALERT® Culture Bottle

1 — Flip Cap
2 — Culture Medium
3 — Sensor
4 — Volume Designations
5 — Barcode
6 — Stopper/Seal

Flip Cap

Plastic flip cap that ensures septum seal cleanliness, but not sterility.

Stopper/Seal

Butyl stopper secured with a color-coded aluminum seal.

Bottle

See Figure E-1.

Volume Designations

Markings which indicate approximate volume in 5 mL increments for adult bottles and 4 mL increments for pediatric bottles. These demarcations assist in approximating the volume of sample added to a bottle.

Barcode

The BacT/ALERT® 3D 60 uses a barcode system to load bottle information. Each BacT/ALERT® bottle has a barcode on its label. For convenience, a portion of this barcode label may be peeled off and affixed to other records (ex. requisition slips). When any other hospital or laboratory label is applied to the bottle, ensure that at least one complete lengthwise portion of the BacT/ALERT® barcode is left visible for proper scanning and that the bottle can be easily removed from its cell.

Entering the barcode commands the BacT/ALERT® 3D 60 system to apply the proper algorithm to the bottle readings.

Occasionally, a BacT/ALERT® barcode label may become unreadable to the barcode scanner (ex. something spilled on the label, the label is covered or torn). If this happens, type in the barcode or apply a generic barcode label (contact your bioMérieux Representative). These labels begin with a "G" or a number and do not contain bottle type information (ex. SA, SN, etc.). Attach the generic BacT/ALERT® barcode label lengthwise on the bottle, not horizontally around the bottle. Do not place the barcode label over the sensor on the bottom of the bottle.

CAUTION: BacT/ALERT® MB Bottles must never be loaded anonymously or with a Generic barcode.

Sensor

Colorimetric carbon dioxide sensor attached internally to the bottom of each bottle.

Limitations of the Test

Refer to the package insert enclosed with the BacT/ALERT® culture bottles for additional information.

Many variables involved in blood culture testing cannot be practically controlled to provide total confidence that results obtained are due solely to proper or improper performance of any culture medium or detection system.

Note: *A Gram-stained smear from a negative bottle may sometimes contain a small number of non-viable organisms that were derived from culture medium components, staining reagents, immersion oil, or glass slides; therefore, false-positive results are indicated.*

Quality Control of Growth Performance

If desired, individual laboratories can perform routine quality control testing of different lots of BacT/ALERT® blood culture bottles when used with the BacT/ALERT® 3D 60 System.

Blood Culture Bottles (SA, SN, FA, FN, and PF)

Each case of BacT/ALERT® blood culture bottles (including BacT/ALERT® SA, SN, FA, FN, and PF) is packaged with a Certificate of Conformance that should be filed for inspection purposes. If additional QC is desired, bottles should be seeded at approximately 400 CFU/bottle using SPS anticoagulated fresh human blood with fresh growth of one or more of the organisms listed on the Certificate of Conformance for each bottle type. The general procedure is described below:

1) Add 1–2 mL blood to the bottle(s).

2) Using growth from solid media which is 18–24 hours old, prepare a suspension in Tryptic Soy Broth (TSB) at 85–90% transmittance at 660 nm or a McFarland 0.5 density (10^8).

3) Perform serial dilutions of this suspension as follows:

a. Dilute 1:100: Pipette 0.1 mL of suspension from Step 2 into 9.9 mL TSB.

b. Dilute 1:100: Pipette 0.1 mL of suspension from Step 3a into 9.9 mL TSB.

c. Dilute 1:10: Pipette 1.0 mL of dilution from Step 3b into 9.0 mL TSB (density should then be approximately 10^3).

4) Inoculate 0.4 mL of the final dilution from Step 3c into the desired adult bottle. If using BacT/ALERT® PF, inoculate 0.2 mL of the final dilution from Step 3c.

5) As soon as possible, load the bottle(s). All aerobic organisms should be positive within 48 hours and all anaerobic organisms within 72 hours.

Mycobacteria Culture Bottles (MB and MP)

Each case of BacT/ALERT® Mycobacteria culture bottles (including MP and MB) is packaged with a Certificate of Conformance that should be filed for inspection purposes. If additional QC is desired, refer to the instructions in the package insert.

GLOSSARY

Accession	A sample collected from a patient during a single event.
Accession ID	Synonym for accession number.
Accession Number	A number that uniquely identifies the sample or patient specimen.
Anonymous Bottle	A bottle that has been placed in an Incubation Chamber without going through the formal bottle loading process. Bottles loaded anonymously must eventually be identified and assigned a bottle ID.
Audible Alarm	Specified by the user to flag positive bottle(s), instrument failure, or an Operator Error.
Audit Trail	Record of activities and other related information (ex. bottle events).
BacT/ALERT®	bioMérieux's automated instrumentation to screen test specimens for the presence of microbes.
Barcode Reader	Used to scan accession numbers or bottle barcode labels and to identify bottles when loading or unloading.
Bottle Graph	A line graph that plots the microbial activity in a culture over time.
Bottle ID	Usually a barcode that uniquely identifies a single culture bottle.
Bottle Type	BacT/ALERT® bottle with a specific type of culture medium (ex. BacT/ALERT® SA).
Cell	Holds and monitors each culture bottle. Each cell is numbered from 1 through 60.
Cell Flag	Secures bottles in cells. Aids in cell diagnostics and with bottle loading and unloading determinations.
Cell Indicator Light	Illuminates to show the location of positive, negative or anonymous bottles as well as to show where new bottles should be placed/removed. A cell indicator light is adjacent to each cell.
Check Box	Textless Yes/No prompt. A check in the box equals **YES** while no check equals **NO**.
CLSI	Clinical and Laboratory Standards Institute

Dimmed	BacT/ALERT® 3D 60 disables (“dims” or “grays”) user interface items (ex. menu items, buttons, text fields) that are unavailable due to security restrictions or due to the current context of the software. Disabled user interface items are not selectable.
Disabled	Describes a user interface item (ex. button, text entry field) that is not currently selectable by the user. Disabled user interlace items are usually displayed in gray.
Enabled	The opposite of disabled.
Field	Refers to an area on the screen where variable text is displayed.
Generic Bottle ID	A Bottle ID that does not indicate one of the pre-defined bottle types.
Grayed	See *dimmed*. Refers to user interface items that are not selectable.
Hospital ID	Text string that uniquely identifies a patient.
Icons	System functions or buttons appearing on-screen in pictorial form.
Indicator Light or Lamp	An identifier for a cell that lights up to indicate location of a particular bottle or bottle-type. They are located on the racks adjacent to the indicated cell.
Keyboard	Provides a means of input for Bottle IDs, Accession Numbers, Hospital IDs, and Names. Also serves as a backup input device should the Touchscreen or Barcode Reader fail.
Laboratory Information System	Name for a customer maintained computer (usually a mainframe) that is used to collect information from laboratory instruments. Abbreviated LIS.
LIS	Acronym for Laboratory Information System.
LIS Port	Connector fitting on the Instrument to connect to a Laboratory Information System.
Monitor	A device upon which video images are displayed.
Negative	Describes a culture bottle that has no evidence of microbial activity.
Negative-to-date	Describes a culture bottle that is under test and negative so far (pending).
NIST	National Institute of Standards and Technology.

Positive	Describes a culture bottle that has evidence of microbial activity.
Power Connector	A fitting to attach the Alternating Current (AC) power cord.
Printer Port	Printer interface port (parallel) on the Instrument for producing hard copy reports and graphs.
Prompt	A text entry field that appears on a screen. The primary purpose for a prompt is for data entry. Read-only prompts are not selectable and are dimmed. User entries into a prompt are checked for validity according to the value range internally assigned for that prompt.
Quick Reference Card	Outlines instructions for system operation and describes specific error codes.
Rack	Contains 20 cells, each of which can hold and monitor an individual culture bottle. Racks gently rock to agitate bottles.
Reference Thermometer	See Thermometer.
Scroll Button	A button that allows selection of numerical or symbolic values by clicking arrows above or below a window which shows the selected character. While an arrow is being clicked, the center portion shows one character from among the available list of choices.
Select	To choose a screen option with a pointing device.
Select Configuration	A BacT/ALERT® 3D 60 configuration where the Instrument is connected to neither an bioMérieux data management computer nor an LIS.
SelectLink Configuration	A BacT/ALERT® 3D 60 configuration where the Instrument is connected directly to an LIS.
Slidebar Switch	A rectangular icon which moves between ON and OFF (symbolized by **1** and **0**, respectively) when the corresponding end of the rectangle is touched.
Thermometer	An independent, NIST-traceable temperature monitoring device.
Toggle Button	A button that becomes active (appears to be clicked) after the corresponding screen area is clicked, and continues to be active until it is clicked again.
Unconfirmed Positive	Describes a bottle the system determined to be positive but no confirmation is available by Gram stain or subculture. Also referred to as a false positive
UPS	Uninterruptible Power Supply (battery backup).

USB Flash Drive	Flash memory storage device integrated with a Universal Serial Bus (USB).
User Interface	The methods by which a computer communicates with the user.

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